

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

AARON ABADI

Plaintiff,

v.

CITY OF NEW YORK

Defendant.

CASE # 1:21-cv-08071-PAE-JLC

AMENDED COMPLAINT

January 12, 2022

JURY TRIAL DEMANDED

Plaintiff, Aaron Abadi, brings this suit, pro se, to permanently enjoin enforcement of the three Executive Orders (“NYC Vaccine Mandates”) that require all employees to be vaccinated and that require thousands of public places as listed therein to not allow the unvaccinated to enter and/or to benefit from their locations and on-site services. Plaintiff hereby complains and alleges the following:

INTRODUCTORY STATEMENT

1) By the spring of 2020, the novel coronavirus SARS-CoV-2, which can cause the disease COVID-19, had spread across the globe. Since then, and because

of the federal government's "Operation Warp Speed," three separate coronavirus vaccines have been developed and approved more swiftly than any other vaccines in our nation's history. The Food and Drug Administration ("FDA") issued an Emergency Use Authorization ("EUA") for the PfizerBioNTech COVID-19 Vaccine ("BioNTech Vaccine") on December 11, 2020. Just one week later, FDA issued a second EUA for the Moderna COVID-19 Vaccine ("Moderna Vaccine").

2) FDA issued its most recent EUA for the Johnson & Johnson COVID-19 Vaccine ("Janssen Vaccine") on February 27, 2021 (the only EUA for a single-shot vaccine).

3) FDA fully approved the Pfizer Comirnaty Vaccine ("Comirnaty Vaccine") on August 23, 2021. Though both are affiliated with Pfizer, the BioNTech Vaccine and the Comirnaty Vaccine are legally distinguishable and on information and belief, the BioNTech and Comirnaty Vaccines are also factually distinguishable.

4) The EUA statute, 21 U.S.C. § 360bbb-3(e)(1)(A)(ii), explicitly states that recipients of products approved for use under it must be informed of the "option to accept or refuse administration," and of the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown."

5) On August 16, 2021 the Mayor of the City of New York issued an Emergency Executive Order # 225, (Exhibit A) relying on the CDC and

“requiring COVID-19 Vaccination for Indoor Entertainment, recreation, Dining and Fitness Settings.” The order states “that a covered entity shall not permit a patron, full- or part-time employee, intern, volunteer, or contractor to enter a covered premises without displaying proof of vaccination and identification bearing the same identifying information as the proof of vaccination.”

6) Additionally, on August 31, 2021, the Mayor of the City of New York issued an Executive Order # 78, (Exhibit B) relying on the CDC and requiring “Mandatory Vaccination or Test Requirement for City Employees and Covered Employees of City Contractors.” This Order requires all City employees and employees of City contractors to either show proof of vaccination, or proof of Covid negative tests each week. The purpose of both these orders and the authority supporting the Mayor’s Order is as stated within the orders, “pursuant to the powers vested in me by the laws of the State of New York and the City of New York, including but not limited to the New York Executive Law, the New York City Charter and the Administrative Code of the City of New York, and the common law authority to protect the public in the event of an emergency.”

7) These Executive Orders require even those recovered from Covid, who have natural immunity, to take the vaccine. Otherwise, they will not be allowed into all these places, and cannot work for the City, or for Contractors to the City.

8) As of December 27, 2021, the newest order by Dr. Dave A. Chokshi, who is the commissioner of the New York City Department of Health and Mental Hygiene, dated Dec 13, 2021 (Exhibit C) went into effect requiring all employers to exclude any employee who was not vaccinated. “Beginning December 27, 2021, workers must provide proof of vaccination against COVID-19 to a covered entity before entering the workplace, and a covered entity must exclude from the workplace any worker who has not provided such proof...”

9) Covered entity is defined as, “a non-governmental entity that employs more than one worker in New York City or maintains a workplace in New York City...” Between the three NYC Vaccine Mandates, the requirement for having a vaccine lays on pretty much on every employer in the city, and on all those tens of thousands of restaurants and public venues listed in the order.

10) The lack of a natural immunity exception, raises serious questions about whether the NYC Vaccine Mandates are designed to accomplish a legitimate purpose. The paucity of exceptions on legitimate bases indicates that the NYC Vaccine Mandates are, at the very least, arbitrary and capricious in addition to being overbroad and poorly designed.

11) Also highlighting the arbitrary nature of the Mandates is the fact that compliance with the NYC Vaccine Mandates can be achieved by receiving any

vaccine that has been listed for emergency use by the World Health Organization (“WHO”).

12) “Proof of vaccination” means proof of receipt of at least one dose of a COVID-19 vaccine authorized for emergency use or licensed for use by the U.S. Food and Drug Administration or authorized for emergency use by the World Health Organization.” Executive Order 225

13) “The term “full vaccination” means at least two weeks have passed after a person received a single-dose of an FDA- or WHO- approved COVID-19 vaccine or the second dose of an FDA- or WHO-approved two-dose COVID-19 vaccine.” Executive Order 78

14) “Fully vaccinated” means at least two weeks have passed after an individual received a single dose of a COVID-19 vaccine that requires only one dose, or the second dose of a two-dose series of a COVID-19 vaccine approved or authorized for use by the Food and Drug Administration or World Health Organization.” Order of the Commissioner

15) Thus, the NYC Vaccine Mandates can be satisfied by taking inferior foreign vaccines that the FDA has *not approved in any fashion*, such as the Sinovac and Sinopharm Vaccines. No credible study has found that these foreign vaccines provide better or even equivalent protection than naturally acquired immunity.

16) Those who do not comply with the NYC Vaccine Mandates by the aggressive deadlines that already passed, face potential disciplinary action, *including termination of employment*, and inability to get employment.

17) Those who enter public places where the NYC Vaccine Mandates are in effect, violating the order, or those entities found violating the order, will be liable for fines ranging from \$1,000 per incident and reaching “not less than \$5,000,” per incident.

18) Plaintiff has already contracted and fully recovered from COVID-19, as evidenced in the letter from his doctor (Exhibit D). As a result, he possesses naturally acquired immunity. It is *medically unnecessary* for individuals with natural immunity to undergo a vaccination procedure at this point (which fact also renders the unnecessary procedure and any attendant risks medically unethical).

19) Yet, if Plaintiff elects not to take the vaccines, he will face adverse disciplinary consequences. In short, the NYC Vaccine Mandates are unmistakably coercive and cannot reasonably be considered anything other than an unlawful order. Furthermore, it represents an unconstitutional condition being applied to Plaintiff’s constitutional and statutory rights to bodily integrity and informed consent, respectively.

20) Given Plaintiff’s naturally acquired immunity, the Defendant cannot establish a compelling governmental interest (or, in the alternative, even satisfy

intermediate scrutiny) in overriding the constitutional rights and personal autonomy of Plaintiff and those who are similarly situated by essentially forcing them to be vaccinated by making their continued employment contingent upon their receiving a COVID-19 vaccine.

21) Plaintiff is unemployed and his unemployment payments ceased in September 2021 (Exhibit E).

22) Plaintiff cannot even apply for a job without being vaccinated. Plaintiff was interested in an available job with the City of New York's Department of Sanitation, as a contract manager, which has been this Plaintiff's line of work for about thirty years. Plaintiff attempted to apply for that job, but was not permitted to even apply for this job as he is not vaccinated (Exhibit F).

23) Naturally acquired immunity is at least as robust and durable as that attained through the most effective vaccines, and it is significantly more protective and long-lasting than some of the inferior foreign vaccines that the NYC Vaccine Mandates accept. As a result, the NYC Vaccine Mandates act to nullify informed consent (since an informed worker and city resident may rationally opt to rely on naturally acquired immunity over vaccine-based immunity) and thus infringes upon Plaintiff's rights, and the rights of those who are similarly situated, under, among others, the Fifth and Ninth Amendments to the United States Constitution.

24) In the Defendant's motion (Doc. 19) she writes, "the challenged EEOs herein do not mandate vaccination but "merely imposes restrictions on those who are not vaccinated..." Based on the repercussions for not vaccinating, that's a pretty distorted view of the NYC Vaccine Mandates.

25) The disciplinary action that the defendant is using to leverage ostensibly voluntary compliance with the NYC Vaccine Mandates is not proportional to their purported public health aims. That renders the NYC Vaccine Mandates an unlawful condition insufficiently germane to its purported purpose.

26) Even beyond its constitutional defects, the unlawful NYC Vaccine Mandates is irreconcilable with and frustrates the objectives of the federal statute governing administration of medical products authorized for emergency use only. That statute is the law of the land, and it trumps mere Executive Orders from the States.

27) Regardless of whether Pfizer recently received full FDA approval for the Comirnaty Vaccine, the remaining vaccines accepted by the NYC Vaccine Mandates have not received it, and (as noted above) the NYC Vaccine Mandates informs all employees that all availability gaps fall on them, not on the federal officials setting the parameters of the mandate. As Pfizer itself acknowledges, the Comirnaty Vaccine is *not widely available* in the United States. And despite its attempts to create equivalence between its BioNTech and Comirnaty Vaccines, the

two are legally distinguishable (and, on information and belief, are factually distinguishable as well). Thus, even after the Comirnaty Vaccine's approval, the NYC Vaccine Mandates still essentially forces individuals, including Plaintiff and those who are similarly situated, to take one of the EUA vaccines (or an unapproved foreign vaccine).

28) In sum, the NYC Vaccine Mandates violate *both* the constitutional *and* federal statutory rights of Plaintiff, because it undermines their bodily integrity and autonomy and conditions his employment and freedom of travel and movement on his willingness to take what for him is a medically unnecessary vaccine.

29) Accepting employment should not mean serving as a guinea pig for emergency use authorized drugs. Forcing Plaintiff and others to take this vaccine will provide no discernible, let alone compelling, benefit either to Plaintiff or to the Defendant.

30) The unconstitutional conditions doctrine exists precisely to prevent government actors from clothing unconstitutional objectives and policies in the garb of supposed voluntarism when those actors fully intend and expect that the pressure they exert will lead to the targets of such disguised regulation succumbing to the government's will. Plaintiff accordingly invokes this Court's Article III and inherent powers to insulate him from this pressure and to vindicate his constitutional and statutory rights.

PARTIES

31) Plaintiff Aaron Abadi's address is at 82 Nassau Street Apt. 140, New York, NY 10038. I am a resident of New York City. Because of the mandate, I cannot get employment in the City of New York, and I am denied access to an endless list of tens of thousands of public spaces.

32) Defendant, City of New York, is located at 100 Church St., 5th Fl., New York, NY 10007.

STATUTORY AND NONSTATUTORY JURISDICTION AND
VENUE

33) The Court has jurisdiction over this case under 28 U.S.C. § 1331: "The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." My claims against the Defendant arise under federal law, specifically the fourteenth amendment of the U.S. Constitution and other federal claims.

34) The Court has the authority to grant declaratory and compensatory relief, and to vacate the NYC Vaccine Mandates under the Declaratory Judgment

Act, and the Court's inherent equitable powers. 28 U.S.C. §§ 2201, 2202; 28 U.S.C. § 1983

35) Venue is proper in this judicial district because the events giving rise to this lawsuit occurred in New York City. "A civil action may be brought in ... a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred ..." 28 U.S.C. § 1391(b)(2).

36) I have standing to sue the Defendant because the Executive Orders restrict my liberties and my freedom of travel and movement, as a resident of New York City, and as a citizen of the United States.

37) I also have standing because as an unemployed resident of New York City, I cannot even apply for a job without being vaccinated. Plaintiff was interested in a job with the City of New York's Department of Sanitation, as a contract manager, which has been this Plaintiff's line of work for about thirty years. Plaintiff tried to apply for the job, but was not permitted to even apply for this job as he is not vaccinated (Exhibit F).

38) A court order declaring unlawful and setting aside the NYC Vaccine Mandates, at least with respect to those with natural immunity, would redress my injuries from continuing, and damages, if provided, will redress the past injuries.

STATEMENT OF FACTS

I. BACKGROUND PERTAINING TO THE CORONAVIRUS PANDEMIC AND COVID-19 VACCINES

39) The novel coronavirus SARS-CoV-2, which can cause the disease COVID-19, is a contagious virus spread mainly from person to person, including through the air.

40) It is well settled that the coronavirus presents a significant risk primarily to individuals aged 70 or older and those with comorbidities such as obesity and diabetes. Joint Declaration of Drs. Jayanta Bhattacharya and Martin Kulldorff filed in a similar case (“Joint Decl.”), ¶¶ 10-14 (Exhibit G). *See* Smiriti Mallapaty, *The Coronavirus Is Most Deadly If You Are Older and Male*, NATURE (Aug. 28, 2020), available at <https://www.nature.com/articles/d41586-020-024832> (last visited Oct. 29, 2021) (individuals 50 years or under face a negligible threat of a severe medical outcome from a coronavirus infection, akin to the types of risk that most people take in everyday life, such as driving a car).

41) In fact, a meta-analysis published by the WHO concluded that the survival rate for COVID-19 patients under 70 years of age was 99.95%. Joint Decl. ¶ 12.

42) CDC estimates that the survival rate for young adults between 20 and 49 is 99.95%, and for people ages 50-64 is 99.4%. Joint Decl. ¶ 12.

43) A seroprevalence study of COVID-19 in Geneva, Switzerland, reached a similar conclusion, estimating a survival rate of approximately 99.4% for patients between 50 and 64 years old, and 99.95% for patients between 20 and 49. Joint Decl. ¶ 13.

44) This past winter, FDA approved three vaccines pursuant to the federal EUA statute, 21 U.S.C. § 360bbb-3.

a. FDA issued an EUA for the BioNTech Vaccine on December 11, 2020.

b. Just one week later, FDA issued an EUA for the Moderna Vaccine.

c. FDA issued its most recent EUA, for the Janssen Vaccine, on February 27, 2021.

d. The Comirnaty Vaccine received full FDA approval on August 23, 2021.

45) In a letter to Pfizer, FDA states that “the Pfizer-BioNTech COVID-19 Vaccine that uses PBS buffer and COMIRNATY (COVID-19 Vaccine, mRNA) have the same formulation. The products are legally distinct with certain differences that do not impact safety or effectiveness.” (emphasis added). FDA,

“Letter to Pfizer, Inc.” (October 29, 2021), *available at*

<https://www.fda.gov/media/150386/download> (last visited Nov. 4, 2021).

46) The Comirnaty Vaccine is *not* widely available due to limited supply, as Pfizer also notes that “there is not sufficient approved vaccine [the Comirnaty] available for distribution to this population in its entirety at the time of the reissuance of this EUA.” *See id.* at p. 9 fn. 7. *See also* FDA, *FDA Approves First COVID-19 Vaccine*, (Aug. 23, 2021), *available at* <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> (last visited Oct. 29, 2021).

47) Indeed, the NYC Vaccine Mandates requires that meeting the deadlines rests exclusively on the shoulders of the employees and residents, availability problems being no excuse at that point, as there is no exception for supply shortages.

48) Information regarding the differences between the BioNTech Vaccine and the Comirnaty Vaccine is not readily available. Generally speaking, certain drugs that the public believes are identical, generic versions of brand name drugs for instance, do not need to be formulaically identical in actuality. FDA, “Generic Drugs: questions & Answers,” *available at* <https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers#q5> (last visited Nov. 4, 2021). Despite

Pfizer's proclamations to the contrary, an analysis of the ingredients in the two indicates they are not, in fact, identical.

49) Recently, a court recognized as much, explaining that inactive ingredients may differ in these circumstances, which can translate into a difference in safety and efficacy. *See Doe v. Austin*, No. 3:21-cv-1211-AW-HTC (N.D. Florida, Nov. 12, 2021), fn. 5.

50) The EUA status of the vaccines that are available at present in the United States means that FDA has not yet fully approved them but permits their conditional use nonetheless due to exigent circumstances.

51) The standard for EUA review and approval is lower than that required for full FDA approval.

52) Typically, vaccine development includes six stages: (1) exploratory; (2) preclinical (animal testing); (3) clinical (human trials); (4) regulatory review and approval; (5) manufacturing; and (6) quality control. *See CDC, Vaccine Testing and the Approval Process* (Exhibit H).

53) The third phase generally takes place over years, because "it can take that long for a new vaccine's side effects to manifest." *id*

54) The third phase must be followed by a period of regulatory review and approval, during which data and outcomes are peer-reviewed and evaluated by FDA. *id*

55) Finally, to achieve full approval, the manufacturer must demonstrate that it can produce the vaccine under conditions that assure adequate quality control.

56) FDA must then determine, based on “substantial evidence,” that the medical product is effective and that the benefits outweigh its risks when used in accordance with the product’s approved labeling. *See CDC, Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19* (Exhibit I).

57) In contrast to this rigorous, six-step approval process that includes long-term data review, FDA grants EUAs in emergencies to “facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic.” FDA, *Emergency Use Authorization for Vaccines Explained* (Exhibit J).

58) EUAs allow FDA to make a product available to the public based on the best available data, without waiting for all the evidence needed for full approval. *See id.*

59) The EUA statute lays out the: “Appropriate conditions designed to ensure that individuals to whom the product is administered are informed.” This means they must be told: that the Secretary has authorized the emergency use of the product; of the significant known and potential benefits and risks of such use,

and of the extent to which such benefits and risks are unknown; and of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks. 21 U.S.C. § 360bbb-3(e)(1)(A)(i).

60) Studies of immunizations outside of clinical-trial settings only began in December 2020, following the first EUA for a COVID vaccine.

II. PRIOR INFECTION LEADS TO NATURALLY ACQUIRED IMMUNITY TO COVID-19 AT LEAST AS ROBUST AS VACCINE-ACQUIRED IMMUNITY

61) Naturally acquired immunity developed after recovery from COVID-19 provides broad protection against severe disease from subsequent SARS-CoV-2 infection. Joint Decl. ¶¶ 15-24.

62) These findings of highly durable natural immunity should not be surprising, as they hold for SARS-CoV-1 and other respiratory viruses. According to a paper published in *Nature* in August 2020, 23 patients who had recovered from SARS-CoV-1 still possess CD4 and CD8 T cells, 17 years after infection during the 2003 outbreak. A *Nature* paper from 2008 found that 32 people born in 1915 or earlier still retained some level of immunity against the 1918 flu strain—

some 90 years later. 10/18/21 Declaration of Dr. Jayanta Bhattacharya (Exhibit K) (“Bhattacharya Decl.”) (Joint Decl.) ¶¶ 49-50.

63) Multiple extensive, peer-reviewed studies comparing naturally acquired and vaccine-acquired immunity have concluded overwhelmingly that the former provides equivalent or greater protection against severe infection than immunity generated by mRNA vaccines (BioNTech and Moderna). Joint Decl. ¶¶ 18-23.

64) These studies confirm the efficacy of natural immunity against reinfection with COVID-19 and show that almost all reinfections are less severe than first-time infections and almost never require hospitalization. Joint Decl. ¶ 18-24.

65) A study from Israel found that vaccinated individuals had 13.1 times greater risk of testing positive, 27 times greater risk of symptomatic disease, and around 8.1 times greater risk of hospitalization than unvaccinated individuals with naturally acquired immunity. (Joint Decl. ¶ 20. & Exhibit L)

66) The authors concluded that the “study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 [BioNTech’s research name] two-dose vaccine-induced immunity.” Joint Decl. ¶ 20.

67) Recent Israeli data found that those who had received the BioNTech Vaccine were 6.72 times *more likely* to suffer a subsequent infection than those with natural immunity. David Rosenberg, *Natural Infection vs. Vaccination: Which Gives More Protection?* ISRAELNATIONALNEWS.COM (Jul. 13, 2021), *available at* <https://www.israelnationalnews.com/News/News.aspx/309762> (last visited Oct. 29, 2021).

68) Israeli data also indicates that the protection BioNTech grants against infection is short lived compared to natural immunity and degrades significantly faster. In fact, as of July 2021, vaccine recipients from January 2021 exhibited only 16% effectiveness against infection and 16% protection against symptomatic infection, increasing linearly until reaching a level of 75% for those vaccinated in April. *See* Nathan Jeffay, *Israeli, UK Data Offer Mixed Signals on Vaccine's Potency Against Delta Strain*, THE TIMES OF ISRAEL (July 22, 2021), *available at* bit.ly/3xg3uCg (last visited Oct. 29, 2021).

69) Those who received a second dose of the BioNTech Vaccine between January and April of this year were determined to have 39% protection against infection and 41% protection against symptomatic infection. The large number of breakthrough infections likely was the result of waning vaccine protection in the face of the Delta variant's spread. *See* Carl Zimmer, *Israeli Data*

Suggests Possible Waning in Effectiveness of Pfizer Vaccine, THE NEW YORK TIMES (July 23, 2021), *available at*

<https://www.nytimes.com/2021/07/23/science/covid-vaccine-israelpfizer.html> (last visited Oct. 29, 2021); Kristen Monaco, *Pfizer Vax Efficacy Dips at 6 Months*, MEDPAGE TODAY (July 29, 2021), *available at* <https://bit.ly/2VheBxw> (last visited Oct. 29, 2021).

70) A CDC/IDSA clinician call on July 17, 2021, summarized the current state of the knowledge regarding the comparative efficacy of natural and vaccine immunity. The presentation reviewed three studies that directly compared the efficacy of prior infection versus mRNA vaccine treatment and concluded “the protective effect of prior infection was similar to 2 doses of a COVID-19 vaccine.”

71) Given that there is currently *more* data on the durability of naturally acquired immunity than there is for vaccine immunity, researchers rely on the expected durability of naturally acquired immunity to predict that of vaccine immunity. Joint Decl. ¶ 23.

72) Indeed, naturally and vaccine-acquired immunity utilize the same basic immunological mechanism—stimulating the immune system to generate an antibody response. Joint Decl. ¶ 16.

73) The level of antibodies in the blood of those who have naturally acquired immunity was initially the benchmark in clinical trials for determining the efficacy of vaccines. Joint Decl. ¶ 16.

74) Studies have demonstrated prolonged natural immunity with respect to memory T and B cells, bone marrow plasma cells, spike-specific neutralizing antibodies, and IgG+ memory B cells following a COVID-19 infection. Joint Decl. ¶ 17.

75) New variants of COVID-19 resulting from the virus's mutation do not escape the natural immunity developed by prior infection from the original strain of the virus. Joint Decl. ¶¶ 29-33; Bhattacharya Decl. ¶ 49-50.

76) While the CDC and the media have touted a study from Kentucky (Exhibit M) as proof that those with naturally acquired immunity should get vaccinated, that conclusion is unwarranted. As Drs. Bhattacharya and Kulldorff explain, although individuals with naturally acquired immunity who received a vaccine showed increased antibody levels afterwards, that does not translate into a clinical benefit. Put otherwise, “[t]his does not mean that the vaccine increases protection against symptomatic disease, hospitalizations or deaths” for those who already acquired natural immunity. Joint Decl. ¶ 37. So, higher antibody levels do not necessarily mean greater protection.

77) The Kentucky study is also problematic because it appears cherry-picked. The CDC gathered data on this subject from all 50 states, but it seems to have chosen to draw attention only to the one state that yielded data that arguably supported its position. *See* Marty Makary, “Covid Confusion at the CDC,” *The Wall Street Journal* (Sept. 13, 2021), *available at* <https://www.wsj.com/articles/covid-19-coronavirus-breakthrough-vaccine-natural-immunitycdc-fauci-biden-failure-11631548306> (last visited Nov. 3, 2021).

78) The CDC has also claimed that another study, of several thousand patients hospitalized with “covid-like illness,” demonstrates the superiority of vaccine-achieved immunity. “Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19 Like Illness,” *CDC* (Oct. 29, 2021), *available at* <https://www.cdc.gov/mmwr/volumes/70/wr/mm7044e1.htm> (last visited Nov. 3, 2021).

79) This study is highly problematic for many reasons experts have pointed out, chief among them that its design meant that it did not actually address the question of whether the covid recovered benefit from being vaccinated. *See* Martin Kulldorff, “A Review and Autopsy of Two COVID Immunity Studies,” *Brownstone Institute* (Nov. 2, 2021), *available at* <https://brownstone.org/articles/a-review-and-autopsy-of-two-covid-immunity-studies/> (last visited Nov. 3, 2021).

80) Rather, “the CDC study answers neither the direct question of whether vaccination or Covid recovery is better at decreasing the risk of subsequent Covid disease, nor whether the vaccine rollout successfully reached the frail. Instead, it asks which of these two has the greater effect size. It answers whether vaccination or Covid recovery is more related to Covid hospitalization or if it is more related to other respiratory type hospitalizations.” *Id.*

81) Kulldorff explains that the Israeli study discussed above, indicating that naturally acquired immunity provides significantly better protection against reinfection, produced far more reliable results due to its design. *Id.*

82) Indeed, shortly after publishing the results of the study, the CDC (much more quietly) conceded that “A systematic review and meta-analysis including data from three vaccine efficacy trials and four observational studies from the US, Israel, and the United Kingdom, found no significant difference in the overall level of protection provided by infection as compared with protection provided by vaccination; this included studies from both prior to and during the period in which Delta was the predominant variant.” “Science Brief: SARA-CoV-2 Infection-induced and Vaccine-induced Immunity,” *CDC* (Oct. 29, 2021), *available at* <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-inducedimmunity.html> (last visited Nov. 3, 2021).

83) In short, contrary to (some of) the claims of the CDC and the media, these studies do *not* establish a valid reason to mandate vaccination of individuals with naturally acquired immunity. *See* Joint Decl. ¶ 37.

84) The Janssen Vaccine provides immunity protection of somewhere between 66% and 85%, far below that conferred by natural immunity. Joint Decl. ¶ 16.

85) The Chinese Sinovac Vaccine has been approved by WHO (making it adequate to satisfy the NYC Vaccine Mandates), which itself determined that this vaccine prevented *symptomatic* disease in just 51% of those who received it. *See WHO Validates Sinovac COVID-19 Vaccine for Emergency Use and Issues Interim Policy Recommendations*, WHO.INT (June 1, 2021), available at bit.ly/3yitIW7 (last visited Oct. 28, 2021).

86) Other clinical studies have found that the Sinovac Vaccine offers even lower levels of protection against infection. For instance, a study of Brazilian healthcare workers determined a mere 50.39% efficacy in preventing infection. *See* Elizabeth de Faria et al., *Performance of Vaccination with Coronavac¹ in a Cohort of Healthcare Workers (HCW)—Preliminary Report*, MEDRXIV (Apr. 15, 2021),

¹ Sinovac and Coronavac are the same. *See* WHO, *Who Validates Sinovac COVID-19 Vaccine For Emergency Use*, (June 1, 2021), available at <https://www.who.int/news/item/01-06-2021-who-validates-sinovac-covid-19-vaccine-for-emergency-use-and-issues-interim-policyrecommendations> (last visited Oct. 29, 2021).

available at <https://www.medrxiv.org/content/10.1101/2021.04.12.21255308v1> (last visited Oct. 29, 2021).

87) Real-world evidence also suggests that the Sinovac Vaccine provides only minimal protection against the Delta variant. *See* Alexander Smith, *China on ‘High Alert’ as Variant of Covid-19 Spreads to 5 Provinces*, NBCNEWS.COM (July 30, 2021), available at [nbcnews.to/2VcK3NB](https://www.nbcnews.to/2VcK3NB) (last visited Oct. 29, 2021); Chao Deng, *As Delta Variant Spreads, China Lacks Data on Its Covid-19 Vaccines*, WALL ST. J. (July 9, 2021), available at on.wsj.com/3rMjlXW (last visited Oct. 29, 2021); Matt D.T. Hitchings, et al., *Effectiveness of CoronaVac in the Setting of High SARS-Cov-2 P.1 Variant Transmission in Brazil: A TestNegative Case-Control Study*, THE LANCET (July 25, 2021), available at bit.ly/3C6F41J (last visited Oct. 29, 2021).

88) The Sinopharm Vaccine, also from China, has likewise received WHO approval. Although its reported level of efficacy against symptomatic infection has been reported as reasonably high (78%), real-world experience has generated severe doubts about the accuracy of that estimate. Because of the Sinopharm Vaccine’s poor performance, several countries have stopped using it. *See* Yaroslav Trofimov & Summer Said, *Bahrain, Facing a Covid Surge, Starts Giving Pfizer Boosters to Recipients of Chinese Vaccine*, WALL ST. J. (June 2, 2021), available at on.wsj.com/3ljM0lX (last visited Oct. 29, 2021).

89) The COVISHIELD vaccine, manufactured by the Serum Institute of India and South Korea's SK Bioscience Co., Ltd., is also WHO-approved and thus recognized as adequate to satisfy the NYC Vaccine Mandates. The WHO itself reported a mere 70.42% efficacy against *symptomatic* COVID-19 infection, which fell to 62.10% in individuals who received two standard doses. *See Recommendation on Emergency Use Listing on COVISHIELD Submitted by SIPL, WHO* (Feb. 26, 2021), *available at* bit.ly/3rNjnPo (last visited Oct. 29, 2021); *Recommendation for an Emergency Use Listing of AZD1222 Submitted by AstraZeneca AB and Manufactured by SK Bioscience Co. Ltd., WHO* (Feb. 23, 2021), *available at* bit.ly/3yiQD3s (last visited Oct. 29, 2021).

90) None of these vaccines have been approved by the FDA for use in the United States. Early data also suggests that naturally acquired immunity provides greater protection against both the Delta and Gamma variants than that achieved through vaccination. A recent analysis of an outbreak among a small group of mine workers in French Guiana found that 60% of fully vaccinated miners suffered breakthrough infections compared to *zero* among those with naturally acquired immunity. Nicolas Vignier, et al., *Breakthrough Infections of SARS-CoV2 Gamma Variant in Fully Vaccinate Gold Miners, French Guiana, 2021*, 27(10) EMERG. INFECT. DIS. (Oct. 2021), *available at*

https://wwwnc.cdc.gov/eid/article/27/10/21-1427_article (last visited Oct. 29, 2021).

91) In this vein, the CDC recently reported that “new scientific data” indicated that vaccinated people who experienced breakthrough infections carried similar viral loads to the unvaccinated (but not naturally immune), leading the CDC to infer that vaccinated people transmit the virus at concerning levels. *See CDC Reversal on Indoor Masking Prompts Experts to Ask, “Where’s the Data?”*, WASHINGTON POST (July 28, 2021), available at [wapo.st/2THpmIQ](https://www.washingtonpost.com/archive/local/2021/07/28/cdc-reversal-on-indoor-masking-prompts-experts-to-ask-where-s-the-data/?hpid=hp_hp-top-table-main-covid-19%3Acdc-reversal-on-indoor-masking-prompts-experts-to-ask-where-s-the-data%3Ahomepage%2Fstory&hpid=hp_hp-top-table-main-covid-19%3Acdc-reversal-on-indoor-masking-prompts-experts-to-ask-where-s-the-data%3Ahomepage%2Fstory) (last visited Oct. 29, 2021). For example, 74% of cases in a Cape Cod outbreak occurred in vaccinated individuals, again demonstrating that the vaccines are inferior to natural immunity when it comes to preventing infection. *See Molly Walker, CDC Alarmed: 74% of Cases in Cape Cod Cluster Were Among the Vaxxed*, MEDPAGE TODAY (July 30, 2021), available at [bit.ly/2V6X3UP](https://www.medicinenet.com/cdc-alarmed-74-of-cases-in-cape-cod-cluster-were-among-the-vaxxed/article.htm) (last visited Oct. 29, 2021).

92) The Omicron Variant seems to be evading all the vaccines, yet natural immunity has been extremely effective against it. The CDC still states that “Covid reinfection is rare,” (Exhibit N), yet when it talks about vaccine breakthrough infections, it says they are to be expected (Exhibit O).

93) The New York Times reports that all the vaccines won’t stop Omicron (Exhibit P).

94) Why are we still living in a world of fantasy? Why can't the politicians admit that our dreams of kicking this completely is wrong? Let's reevaluate and make rational decisions based on actual scientific data. Again, why would it make any sense to force a person who has natural immunity?!

III. COVID-19 VACCINES CAN CAUSE SIDE EFFECTS, INCLUDING SEVERE ADVERSE REACTIONS

95) Though the COVID-19 vaccines appear to be relatively safe at a population level, like all medical interventions, they carry a risk of side effects. Those side effects include common, temporary reactions such as pain and swelling at the vaccination site, fatigue, headache, muscle pain, fever, and nausea. More rarely, they can cause serious side effects that result in hospitalization or death. Joint Decl. ¶¶ 25-26.

96) The vaccines could cause other side effects that remain unknown at this time due to their relatively recent development. Joint Decl. ¶¶ 26-27.

97) Put differently, as a matter of simple logic, one cannot be certain about the long-term effects of vaccines that have not been in existence for the long term and thus cannot have been studied over a span measured in years instead of

months. For that reason, “[a]ctive investigation to check for safety problems is still ongoing.” Joint Decl. ¶ 26.

98) For example, vaccine-related myocarditis is associated with a significant leak of cardiac enzymes from the heart and thus can result in permanent heart damage. 12/20/21 Declaration of Dr. Anish Koka (“Koka Decl.”)(Exhibit Q).

99) Although vaccine myocarditis is associated with reduction of heart function that appears to normalize quickly, cardiac magnetic resonance imaging (“MRI”) has been finding the formation of scar tissue after vaccine myocarditis that is similar to findings in non-vaccine myocarditis. Koka Decl. ¶ 12.

100) Early evidence suggests that about one-third of patients who suffer an episode of vaccine myocarditis have evidence of scar/fibrosis, seen in a 3-month follow up. Koka Decl. ¶ 13.

101) This could have long-term consequences. A systemic review of literature found that the presence of scar tissue detected by cardiac MRI is associated with an increased risk of death, heart failure, need for cardiac transplantation, and serious cardiac arrhythmias. Koka Decl. ¶ 14.

102) While some of have argued that the risk of myocarditis from contracting COVID19 is higher than that from vaccines, a study in the Journal of

American Medical Association demonstrated that diagnosis of myocarditis peaked only after widespread vaccine administration. Koka Decl. ¶ 15.

103) Moreover, this risk/benefit calculus does not account for those with naturally acquired immunity.

104) In sum: vaccine related myocarditis is a *potentially serious* medical condition that can lead to fibrosis in heart muscle. Fibrosis and scarring found within the heart muscle has been associated with *long term complications* related to cardiac arrhythmias and even sudden cardiac death. It is not yet known what the long-term sequelae will be for those patients who have developed scarring and fibrosis related to vaccine myocarditis. Rates of vaccine myocarditis in certain sub-populations may exceed the risks from SARS-Cov2 associated myocarditis (emphasis added). Koka Decl. ¶ 17.

105) Recent research indicates that vaccination presents a heightened risk of adverse side effects—including serious ones—to those who have previously contracted and recovered from COVID-19. Joint Decl. ¶ 28; Bhattacharya Decl. ¶30.

106) The heightened risk of adverse effects results from “preexisting immunity to SARSCov-2 [that] may trigger unexpectedly intense, albeit relatively rare, inflammatory and thrombotic reactions in previously immunized and predisposed individuals.” Angeli *et al.*, *SARS-CoV-2 Vaccines: Lights and*

Shadows, 88 EUR. J. INTERNAL MED. 1, 8 (2021). *See also* Jennifer Block, “Vaccinating people who have had covid-19: why doesn’t natural immunity count in the US?” BRITISH MEDICAL JOURNAL (Sept. 13, 2021), *available at* <https://www.bmj.com/content/374/bmj.n2101> (last viewed Dec. 13, 2021) (citing several experts and studies establishing that those who have previously been infected are more likely to experience adverse side effects from the vaccines).

107) Vaccination of the naturally immune may actually increase their chances of reinfection. Some experts believe that subsequent vaccination (especially a two-dose regimen) for those who have been previously infected may cause “‘exhaustion,’ and in some cases even a deletion, of T-cells,” leading to a depleted immune response.

108) There are links to hundreds of studies, or maybe a thousand, listed in Exhibit R, that show significant and dangerous adverse effects from the Covid vaccines. This is just what we know now. The long-term effects may be significantly worse. We haven’t had the time for real data yet.

109) The Vaccine Adverse Event Reporting System (“VAERS”) is a joint project between the FDA and the CDC. It tracks adverse events from vaccines. The database is extensive. You can see from a compilation of data from VAERS (Exhibit S) that the adverse reactions to the Covid vaccines in just this one

year already exceed all adverse reaction claims for all vaccines since 1990. This cannot be taken lightly.

110) Substantial scientific literature demonstrates that, while the COVID-19 vaccines carry the possibility of side effects for anyone, as do all medical procedures, the risk of harm is greater to those who have recovered from the disease. *id*

111) Accordingly, mandating that Plaintiff receive a COVID-19 vaccine violates fundamental tenets of medical ethics.

112) Plaintiff has real, substantial, and legitimate concerns about taking a COVID-19 vaccine in light of his natural immunity and the potential for short- and long-term side effects and potential adverse reactions from the vaccines themselves.

IV. PLAINTIFF HAS EXPERIENCED, AND WILL CONTINUE TO EXPERIENCE, CONCRETE AND PARTICULARIZED HARM AS A DIRECT CONSEQUENCE OF THE NYC VACCINE MANDATES

113) Plaintiff either must receive a COVID-19 vaccine or face the inability to get employment. Plaintiff has been banned from and continues to be banned from tens of thousands of public places throughout the city. Accordingly, Plaintiff's personal autonomy and livelihood are being infringed.

114) By presenting these adverse professional and personal consequences, the NYC Vaccine Mandates not only directly and palpably harms Plaintiff's bodily autonomy and dignity, but it forces him to endure the stress and anxiety of choosing between employment, upon which he and his family relies on, and his health.

115) The ostensible (and non-existent in the case of naturally immune employees) risk avoidance benefits that the NYC Vaccine Mandates implementation provides, compared to the restrictions and intrusive options offered to Plaintiff, are disproportionate. Given that naturally acquired immunity confers equal or greater protection than that provided by the vaccines (especially with respect to some of the WHO-approved vaccines that Defendant consider adequate to fulfill the NYC Vaccine Mandates' requirements), those mandates are arbitrary and irrational.

116) There is no indication that the NYC Vaccine Mandates are tailored to account for its impact on those who have acquired natural immunity. In fact, official explanations of this mandate specifically refuse to recognize those with natural immunity as posing different issues and requiring different treatment as compared to unvaccinated individuals who lack natural immunity. It is especially arbitrary and irrational to require a vaccine that was not designed for the current,

widely circulating Omicron variant and that has been shown to be far less effective against the Omicron variant than it was against earlier variants.

V. THIS VACCINE IS VERY DIFFERENT THAN IN PREVIOUS CASE LAW

117) In *Jacobson v. Massachusetts*, 197 US 11 - Supreme Court 1905, it states that due to public health, forced vaccinations are allowed, and it is likely that the Defendant is relying on this, as submitted in her motion. However, the case is actually a bit different than our situation today. It says, “Since then vaccination, as a means of protecting a community against smallpox, finds strong support in the experience of this and other countries, no court, much less a jury, is justified in disregarding the action of the legislature simply because in its or their opinion that particular method was — perhaps or possibly — not the best either for children or adults.”

118) It's referring to an outbreak of small pox, that is a contagious, disfiguring and often deadly disease that has affected humans for thousands of years. Naturally occurring smallpox was wiped out worldwide by 1980, as the result of an unprecedented global immunization campaign. (See Exhibit T) .

119) Small pox is no comparison. If I were alive during the time of that case, I would be a strong advocate for forcing the small pox vaccine. It was a real

vaccine that actually wiped the disease out. The current Covid vaccines that we have aren't wiping anything out. They're possibly slowing it down.

120) I had measles as a child. No one ever suggested that I should also get the vaccine anyway. That would have been absurd.

121) Years later, within the last several years, I was recommended by my doctor to take a blood test to see if I still had strong enough measles immunity. The natural immunity hardly wanes, but vaccine immunity from 40-50 ago often weakened.

122) As it turned out, my immunity to measles and mumps were as strong as ever. Unfortunately, for rubella, I had no immunity. I probably never had the Measles, Mumps, and Rubella ("MMR") as a kid. So, I immediately took the MMR shot to protect from Rubella, as I travel a lot and although Rubella is mostly non-existent, I'd rather be safe than sorry.

123) Additionally, in the small pox scenario, there were no cures available, and those who caught it had it very rough. The only solution was to eradicate it.

124) Covid has many therapeutics that work well. An overwhelming percentage survive with no long-term health issues.

COUNT I: VIOLATION OF THE RIGHT TO REFUSE UNWANTED

AND MEDICALLY UNNECESSARY CARE

125) Plaintiff reallege and incorporate by reference the foregoing allegations as if fully set forth herein.

126) The NYC Vaccine Mandates require Plaintiff to take a vaccine without his consent—and against the medical advice of experts—thereby depriving him of his ability to refuse unwanted medical care.

127) The Supreme Court has recognized that the Fifth, Ninth and Fourteenth Amendments protect an individual’s right to privacy. A “forcible injection ... into a nonconsenting person’s body represents a substantial interference with that person’s liberty[.]” *Washington v. Harper*, 494 U.S. 210, 229 (1990). The common law baseline is also a relevant touchstone out of which grew the relevant constitutional law. *See, e.g., Cruzan v. Dir., Mo. Dep’t of Public Health*, 497 U.S. 261, 278 (1990) (““At common law, even the touching of one person by another without consent and without legal justification was a battery”). *See* W. Keeton, D. Dobbs, R. Keeton, & D. Owen, PROSSER AND KEETON ON LAW OF TORTS § 9, pp. 39-42 (5th ed. 1984.); *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 129-130, 105 N.E. 92, 93 (1914) (Cardozo, J.) (“Every human being of adult years and sound mind has a right to determine what shall be

done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.”).

128) “The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty.” Cf. *Winston v. Lee*, 470 U. S. 753 (1985); *Schmerber v. California*, 384 U. S. 757, 772 (1966).

129) Subsequent Supreme Court decisions have made explicit that the Constitution protects a person's right to “refus[e] unwanted medical care.” *Cruzan*, 497 U.S. at 278; *King v. Rubenstein*, 825 F.3d 206, 222 (4th Cir. 2016) (recognizing same).

130) This right is “so rooted in our history, tradition, and practice as to require special protection under the Fourteenth Amendment.” *Washington v. Glucksberg*, 521 U.S. 702, 722 n.17 (1997).

131) The Court has explained that the right to refuse medical care derives from the “well established, traditional rights to bodily integrity and freedom from unwanted touching.” *Vacco v. Quill*, 521 U.S. 793, 807 (1997).

132) The Ninth Amendment similarly protects the rights to privacy and bodily integrity. *See Griswold v. Connecticut*, 381 U.S. 479, 488 (1965) (Goldberg, J., concurring) (“The language and history of the Ninth Amendment reveal that the Framers of the Constitution believed that there are additional fundamental rights, protected from governmental infringement, which exist

alongside those fundamental rights specifically mentioned in the first eight constitutional amendments.”).

133) Coercing employees to receive a vaccine (whether approved under an EUA or fully by the FDA) for a virus that presents a near-zero risk of illness or death to them and which they are exceedingly unlikely to pass on to others because those employees already possess natural immunities to the virus, violates the liberty and privacy interests that the Fifth and Ninth Amendments protect.

134) The vast majority of the New York City workforce is vaccinated, so this plaintiff poses no conceivable cognizable harm to them even under the Defendant’s asserted views of the facts.

135) “Government actions that burden the exercise of those fundamental rights or liberty interests [life, liberty, property] are subject to strict scrutiny, and will be upheld only when they are narrowly tailored to a compelling governmental interest.” *Does v. Munoz*, 507 F.3d 961, 964 (2007).

136) Defendant cannot show that they have a compelling interest in coercing Plaintiff or others similarly situated into taking a COVID-19 vaccine, because Defendant has no compelling interest in treating people with naturally acquired immunity any differently from people who obtained immunity from a vaccine. Nor, in light of the NYC Vaccine Mandates arbitrariness and evidentiary defects, could the NYC Vaccine Mandates satisfy intermediate scrutiny.

137) In any event, unless the Courts carefully review government claims of emergency and compelling interests, the rights protected by the Constitution will be forfeit to the City's mere assertion of such conditions.

138) Substantial research establishes that a COVID-19 infection creates immunity to the virus at least as robust, durable, and long-lasting as that achieved through vaccination. Joint Decl. at ¶¶ 15-24; Nabin K. Shrestha, et al., *Necessity of COVID-19 Vaccination in Previously Infected Individuals*, MEDRXIV (June 5th, 2021), available at <https://bit.ly/2TFBGcA> (last visited Oct. 29, 2021); see also Yair Goldberg, et al., *Protection of Previous SARS-Cov-2 Infection Is Similar to That of BNT162b2 Vaccine Protection: A Three-Month Nationwide Experience from Israel*, MEDRXIV (Apr. 20, 2021), available at <https://bit.ly/3zMV2fb> (last visited Oct. 26, 2021); Michael Smerconish, *Should Covid Survivors and the Vaccinated Be Treated the Same?*: CNN Interview with Jay Bhattacharya, Professor of Medicine at Stanford University (June 12, 2021), available at <https://cnn.it/2WDurDn> (last visited Oct. 29, 2021); Marty Makary, *The Power of Natural Immunity*, WALL STREET JOURNAL (June 8, 2021), available at <https://on.wsj.com/3yeu1Rx> (last visited Oct. 29, 2021).

139) In recognition of the highly protective character of natural immunity, the European Union has recognized “a record of previous infection” as a substitute for any vaccine passport requirements. Israel, too, exempts from vaccination

requirements those who are COVID-19 recovered. *See, e.g.*, “Covid passports: How do they work around the world?”, *BBC News* (July 26, 2021), *available at* <https://www.bbc.com/news/world-europe-56522408>.

140) Even France’s controversial new restrictive mandate on the ability to participate in daily life focuses on a person’s immunity rather than their vaccine status—treating natural immunity and vaccine immunity equally. *See, e.g.*, Clea Callcutt, *France forced to soften rules after coronavirus green pass backlash*, *POLITICO* (July 20, 2021), *available at* <https://politi.co/3f9AZzS> (last visited July 29, 2021).

141) Similarly, the United States requires everyone, including its citizens, to provide proof of a negative COVID-19 test before returning to the country from abroad. Yet, documentation of recovery suffices as a substitute, although proof of vaccination does not. *See Requirement of Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States*, CDC (July 6, 2021), *available at* <https://bit.ly/3yfcJDM> (last visited Oct. 29, 2021).

142) Recent data from Israel suggests that individuals who receive the BioNTech Vaccine can pass the virus onto others a mere few months after receiving it, casting doubt on any claim that the vaccine prevents spread of the

virus, or at least any claim that it does so to a greater extent than naturally acquired immunity.

143) Defendant offers no compelling interest in departing from the import of the science on natural immunity.

144) For similar reasons that Defendant fails to advance a valid governmental interest in requiring that already immune employees get vaccinated, Defendant cannot show that the NYC Vaccine Mandates are narrowly tailored to meet any such governmental interest.

145) That is because any interest that Defendant may have in promoting immunity does not extend to those people who can demonstrate that they already have naturally acquired immunity, through antibody testing or a positive Covid PCR test.

146) This provides evidence that Defendant is trying to avoid the difficulties associated with allowing medical decisions to be made based on personal circumstances, rather than attempting to promote a legitimate public health aim.

147) The CDC concedes that so-called breakthrough cases exist. And, in the course of doing so, the CDC actually acknowledges a lack of a public health basis for its vaccine policy: Vaccine breakthrough cases are expected. COVID-19 vaccines are effective and are a critical tool to bring the pandemic under control;

however, no vaccine is 100% effective at preventing illness. Some fully vaccinated people will get sick, and some will even be hospitalized or die from COVID-19. *However, there is evidence that vaccination may make illness less severe for those who are vaccinated and still get sick.* CDC, *COVID-19 Vaccine Breakthrough Case Investigation and Reporting*, available at <https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html> (last visited Oct. 29, 2021) (emphasis added). The italicized text represents an individualized benefit of vaccination, not a public health one.

148) In other words, CDC does not pretend that vaccine mandates are truly about protecting others, since naturally acquired immunity also prevents hospitalizations, severe disease, and death. And this point certainly drives home the arbitrary nature of the government’s apparent position that robust, naturally acquired immunity should be disregarded, while only the more limited immunity acquired through vaccination—even from inferior foreign vaccination—should be recognized. Thus, this mandate infringes on Plaintiff’s bodily autonomy with no valid public health justification.

149) Indeed, the refusal to recognize naturally acquired immunity is a phenomenon unique to this pandemic and this country. Even the United States military exempts individuals who can demonstrate naturally acquired immunity to the disease in question from the requisite vaccine mandate. *See* “Immunization

Exception Guidance,” *The Official Website of the Military Health System*, available at <https://www.health.mil/Military-Health-Topics/HealthReadiness/Immunization-Healthcare/Clinical-Consultation-Services/Exemption-Guidance> (last visited Oct. 29, 2021).

150) In sum, Defendant’s implicit justifications for the NYC Vaccine Mandates are speculative, logically incoherent, and not designed to protect the health and safety of the people and employees. There is no need to protect anyone from unvaccinated people who possess naturally acquired immunity, because those people do not pose a risk.

151) Another reason the NYC Vaccine Mandates lack any constitutional validity is that many of the vaccines that they accept, such as the Janssen, Sinovac, and Sinopharm vaccines are much less effective when it comes to preventing infection than natural immunity. Plaintiff is, therefore, significantly less likely to contract or spread the virus than others who have been immunized with these inferior vaccines. Yet Plaintiff is subject to the inability to be employed, and the restriction of travel and movement, while those others with inferior immunity are not.

152) By failing to tailor the NYC Vaccine Mandates to only those people who lack immunity of any kind, Defendant irrationally forces potential employees and residents like Plaintiff (and those similarly situated), who have naturally

acquired immunity, to choose between their health, their personal autonomy, and their careers.

153) Plaintiff has suffered and will continue to suffer damage from Defendant's conduct. There is no adequate remedy at law, as there are no damages that could compensate Plaintiff for the deprivation of their constitutional rights. He will continue to suffer irreparable harm unless this Court enjoins Defendant from enforcing the NYC Vaccine Mandates against people with natural immunity. Once an employee is forced to take the vaccine, there is no way to unring that bell. Any harm is therefore irreparable. *See Fraternal Order of Police Chicago Lodge No. 7 v. City of Chicago*, Case No, 2021 CH 5276 (Ill. Cir. Ct. Nov. 1, 2021) ("If every union member complied and was vaccinated by December 31 (or otherwise exempt), they would have no grievance to pursue and there would be no remedy an arbitrator could award. An award of back pay or reinstatement cannot undo a vaccine. Nothing can."). There is no option to be tested or wear masks in most cases here as an alternative. Thus, the harm here is even greater than in *BST Holdings, LLC et al. v. OSHA*, __F.4th __, 2021 WL 5279381 *8 (5th Cir.), in which the court found that having to choose between "jobs" and "jabs" constitutes irreparable harm, even though masking and testing was offered as an alternative.

154) Plaintiff is entitled to a judgment declaring that the NYC Vaccine Mandates violate his constitutional rights to refuse medical treatment and an injunction restraining Defendant's enforcement of these mandates.

**COUNT II: VIOLATION OF THE UNCONSTITUTIONAL
CONDITIONS DOCTRINE AND THE FOURTEENTH AMENDMENT'S
RIGHT TO DUE PROCESS OF LAW**

155) Plaintiff reallege and incorporate by reference the foregoing allegations as if fully set forth herein.

156) Unconstitutional conditions case law often references the existence of varying degrees of coercion. According to that body of law, Defendant cannot impair Plaintiff's right to refuse medical care through subtle forms of coercion any more than it could through an explicit mandate. *See, e.g., Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595 (2013) (“[U]nconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them”); *Memorial Hosp. v. Maricopa Cty.*, 415 U.S. 250 (1974) (finding that state residency requirement impinged on the constitutionally guaranteed right to interstate travel, while lacking a compelling state interest, and thus was unconstitutional).

157) Plaintiff claims that being that he already had Covid, he should not be subject to such rules and should be treated the same as someone who was vaccinated. Plaintiff presents here that by requiring vaccination in order to enter a large percentage of the businesses in the City, and by requiring vaccinations for employment anywhere in the City, the City of New York is violating the Plaintiff's Constitutional Rights under the Fourteenth Amendment.

158) The Fourteenth Amendment's due process clause provides heightened protection against government interference with certain fundamental rights and liberty interests. Sanchez, 914 F. Supp. 2d at 1100-01 (quoting Glucksberg, 521 U.S. at 720). Plaintiff's constitutional right to bodily integrity is impinged by the Executive Orders.

159) Requiring someone to vaccinate, who already had Covid and thus has natural immunity is arbitrary and capricious. The person already has protection, which is likely a better protection than the vaccine, and certainly much better than many of the inferior vaccines accepted.

160) The Executive Orders are clearly an attempt to coerce everyone, even those with natural immunity to get vaccinated. Being that this is not really necessary for those recovered from Covid for the emergency purpose, and has no provable health benefits or protections against Covid, coercing and requiring Plaintiff to get vaccinated is a violation of his rights under the Constitution.

161) The United States Constitution guarantees that state governments shall not deprive any person of life, liberty, or property without due process of law, U.S. CONST. amend. XIV § 1, and forbids the government to infringe certain fundamental liberty interests at all, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest. *Reno v. Flores*, 507 U.S. 292, 301-02 (1993). These Executive Orders do not serve any compelling State interest with respect to requiring those with natural immunity to get vaccinated.

162) *Lake Shore & Michigan Southern R. Co. v. Smith*, 173 US 684 - Supreme Court 1899 states that Police Power must still be subject to Constitutional law, and that Equal application of the law and due process rights cannot be violated.

163) “The police power is a general term used to express the particular right of a government which is inherent in every sovereignty. As stated by Mr. Chief Justice Taney, in the course of his opinion in the License cases, 5 How. 504, 583, in describing the powers of a State: "they are nothing more or less than the powers of government inherent in every sovereignty to the extent of its dominions. And whether a State passes a quarantine law, or a law to punish offences, or to establish courts of justice, or requiring certain instruments to be recorded, or to regulate commerce within its own limits, in every case it exercises the same power; that is to say, the power of sovereignty, the power to govern men and things within the limits of its dominion. This power must, however, be exercised in subordination to the

provisions of the Federal Constitution. If, in the assumed exercise of its police power, the legislature of a State directly and plainly violates a provision of the Constitution of the United States, such legislation would be void.”

164) Plaintiff confirms the following: Plaintiff is not anti-vaccines. On the contrary, Plaintiff has taken every vaccine recommended by his doctors, including even a measles vaccine in 2021, even though he had the disease as a child. That was based on the science and actual data, not conjecture. Plaintiff appreciates, respects, and understands the desperate attempt to force vaccines on the unvaccinated that never had Covid. Plaintiff’s only issue here is the forcing of vaccines on those who already have natural immunity.

165) The Supreme Court has recognized that the Ninth and Fourteenth Amendments protect an individual’s right to privacy. A “forcible injection ... into a nonconsenting person’s body represents a substantial interference with that person’s liberty[.]” *Washington v. Harper*, 494 U.S. 210, 229 (1990). The common law baseline is also a relevant touchstone out of which grew the relevant constitutional law. See, e.g., *Cruzan v. Dir., Mo. Dep’t of Public Health*, 497 U.S. 261, 278 (1990) (“‘At common law, even the touching of one person by another without consent and without legal justification was a battery’). See W. Keeton, D. Dobbs, R. Keeton, & D. Owen, *PROSSER AND KEETON ON LAW OF TORTS* § 9, pp. 39-42 (5th ed. 1984).); *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 129-130, 105 N.E.

92, 93 (1914) (Cardozo, J.) ('Every human being of adult years and sound mind has a right to determine what shall be done with his own body).

166) Plaintiff is naturally immune to SARS-CoV-2. Therefore, Plaintiff is at least as equally situated as to not be considered a health risk, as those who are fully vaccinated with a COVID-19 vaccine, yet Defendant denies Plaintiff equal treatment and seeks to burden Plaintiff with an unnecessary violation of bodily integrity to which Plaintiff does not consent in order to be allowed to apply for a job, go to the gym, eat in a restaurant, or do any one of a million other normal activities and necessary actions that others are permitted to do.

167) The Fourteenth Amendment, Section 1, to the United States Constitution provides: No state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any state deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

168) Plaintiff possesses both a liberty interest in maintaining his bodily integrity and a property interest in his career, an interest in free travel and movement, and as well as statutory and constitutional interests in the right to refuse EUA vaccines.

169) When a government policy burdens a constitutional right by imposing undue pressure on an otherwise voluntary choice with a nexus to the exercise of a constitutional right it imposes as unconstitutional condition.

170) In other words, the presence of some remaining voluntarism after new conditions are imposed on the exercise of a constitutional right does not stand as a barrier to mounting a successful unconstitutional conditions claim. This is especially true when a government actor couples an unconstitutional condition with a procedural system stacked against the right-holder.

171) For example, in *Speiser v. Randall*, 357 U.S. 513 (1958), the Court invalidated a loyalty oath imposed as a condition for veterans to obtain a state property tax exemption, even though (a) California citizens were not required to own real property, of course; (b) California veterans could freely opt not to seek the exemption and simply pay the unadorned tax; and (c) California was not even obligated to provide veterans with the exemption but rather the exemption was a mere privilege.

172) The *Speiser* Court deemed the oath condition unconstitutional in part because the burden to establish qualification for the exemption was placed on applicants. *See id.* at 522. The question the Supreme Court saw itself deciding was “whether this allocation of the burden of proof, on an issue concerning freedom of speech, falls short of the requirements of due process.” *Id.* at 523.

173) The Court addressed this question by stating the guiding principle that where one party has at stake an interest of transcending value—as a criminal defendant his liberty—this margin of error is reduced as to him by the process of placing on the other party the burden of producing a sufficiency of proof in the first instance [But] Due process commands that no man shall lose his liberty unless the Government has borne the burden of producing the evidence and convincing the factfinder of his guilt. *Id.* at 525-26.

174) Here, the analogue of the criminal defendant rights of “transcending value” referenced in *Speiser* are the liberty rights of all persons to be free from unconsented-to bodily intrusions and unnecessary medical interventions. This means that unconstitutional conditions doctrine and due process rights *combine* to invalidate the NYC Vaccine Mandates. That result occurs because Defendant has not and cannot show that forcing the Plaintiff and those similarly situated to take the vaccine reduces any risk that they will become infected with and spread the virus to other personnel or to customers in the workplace, or in indoor public venues that are included in the mandates.

175) Similar to the California law in *Speiser* “creat[ing] the danger that ... legitimate utterance will be penalized,” 357 U.S. at 526, the process Defendant have established in relation to taking COVID-19 vaccines poses dangers to

Plaintiff's health (and thus to his liberty interest) as well as threatening him with penalties if he does not comply.

176) Indeed, more so than in *Speiser*, the factual issues involved in this case are complex. "How can a claimant ... possibly sustain the burden of proving the negative of these complex factual elements? In practical operation, therefore, this procedural device must necessarily produce a result which the State could not command directly." *Id.* There is perhaps no better encapsulation than the preceding sentence by the Supreme Court of how unconstitutional conditions doctrine and procedural due process can and do intersect and reinforce one another. *See also id.* at 529 ("The State clearly has no such compelling interest at stake as to justify a shortcut procedure which must inevitably result in suppressing protected speech."). Defendant similarly possesses no compelling interest that could justify its defective NYC Vaccine Mandates that will inevitably result in at least some unwarranted medical intrusions into the bodies of members of the community of New York City employees, residents, and visitors, and, importantly, possible harm to the plaintiff from getting vaccinated.

177) For these reasons, Defendant cannot by means of its NYC Vaccine Mandates effectively flip the burden of proof and require Plaintiff and others similarly situated to prove that it is safe for them to perform their respective jobs while unvaccinated. And setting up such a deficient process, which is what the

NYC Vaccine Mandates does, thereby represents a concurrent *procedural due process of law violation and* an unconstitutional condition burdening Plaintiff's liberty interests to be free of unwanted, unnecessary medical interventions.

178) *Speiser* also rests on the mismatch between the loyalty oath California required and the grant of a property tax exemption to veterans. “[T]he State is powerless to erase the service which the veteran has rendered his country; though he be denied a tax exemption, he remains a veteran.” *Id.* at 528.

179) In this situation, there is an equally jarring logical incongruity. Defendant's NYC Vaccine Mandates are relatively terse. They offer no justifications for why the penalties and other restrictions it establishes are appropriate and tailored to members of the New York City community who have acquired robust natural immunity. Whatever Defendant is trying to decree through its unconstitutional-conditions sleight of hand, Plaintiff remain a New York City resident with natural immunity as a matter of fact (just as the *Speiser* veterans remained veterans as a matter of pre-tax-law fact), and the existence of such immunity fully serves the supposed purposes of the public-health protection that Defendant says that they are pursuing.

180) The proportionality of the NYC Vaccine Mandates is also deficient because it does not seek to assess the current antibody levels of its targets,

something that it is now feasible for medical science to test.² This deficiency means that many New Yorkers who are vaccinated but for some reason fail to develop sufficient antibody levels are treated more favorably than the naturally immune who in fact possess more robust immunity levels.

181) The NYC Vaccine Mandates are not a mere initial presumption that vaccination is superior to natural immunity (a contention that would have to be borne out by the science in any event or else Defendant had no business adopting their NYC Vaccine Mandates), which Plaintiff might at least try to overcome.

182) The NYC Vaccine Mandates are, in essence, *a conclusive presumption* (and thus a procedural due process of law violation) that vaccination is required (even as to vaccines of far-lesser efficacy) for all employees and residents, regardless of their antibody levels or COVID recovered status, unless the risks of the vaccine to a particular recipient warrant a special exception.

183) But Plaintiff and others with naturally acquired immunity possess more robust immunity than those who took one or more of the various inferior

² Such antibody testing was not possible more than a century ago when *Jacobson v. Massachusetts* was decided, as diagnostic antibody testing was not invented until the 1970's. 197 U.S. 11 (1905) (upholding a city regulation fining individuals \$5 if they refused to take Smallpox vaccine). See *The History of ELISA from Creation to COVID-19 Research*, MOLECULAR DEVICES, available at <https://www.moleculardevices.com/lab-notes/microplate-readers/the-history-of-elisa> (last visited Oct. 29, 2021).

vaccines that Defendant accepts and equivalent or greater levels to those who took the mRNA vaccines approved by the FDA.

184) Defendant has, in essence, deemed all vaccines to be equally protective in the fictitious presumption they have established. There is no scientific basis whatsoever for the false suppositions that Defendant has built into the NYC Vaccine Mandates.

185) For the foregoing reasons, the *de facto* presumptions the NYC Vaccine Mandates establish become another part of Defendant's procedural due process of law violations that run afoul of unconstitutional conditions doctrine. In short, by allocating burden-of-proof responsibility to those with natural immunity like Plaintiff, coupled with Defendant's stacking the process deck with presumptions that Plaintiff has shown are scientifically unwarranted, Defendant contravenes the Due Process Clause. *See Perry v. Sinderman*, 408 U.S. 592, 597 (1972) (holding that the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests"); *Wieman v. Updegraff*, 344 U.S. 183, 192 (1952) ("We need not pause to consider whether an abstract right to public employment exists. It is sufficient to say that constitutional protection does extend to the public servant whose exclusion pursuant to a statute is patently arbitrary or discriminatory.").

COUNT III: THE NYC VACCINE MANDATES VIOLATE THE
EQUAL PROTECTION COMPONENT OF THE DUE PROCESS CLAUSE
OF THE FOURTEENTH AMENDMENT

186) Plaintiff realleges and incorporates by reference all the foregoing allegations as though fully set forth herein.

187) Plaintiff claims that these Executive Orders denies his rights to Equal Protection under the Constitution. Plaintiff is the same or more immune to the Covid disease as a vaccinated individual, yet the vaccinated individual can go to all these places and take any job, while Plaintiff is severely limited by these Orders.

188) Equal protection problems are compounded because individuals with naturally acquired immunity are at a disadvantage when it comes to vaccination, since immunization poses a greater risk of harm to them than to those who are unvaccinated and have not acquired immunity naturally. Thus, through no fault of their own, Plaintiff are in a position where they would have to expose themselves to a heightened risk of adverse side effects (without gaining any concurrent or greater benefit for third parties).

189) Equal protection problems are also compounded because the NYC Vaccine Mandates effectively creates, at least prior to the separation of disciplined workers from federal service, two classes of workers—those allowed relative

freedom to continue to work and those denied such freedoms and saddled with employment fetters and discipline, without any rational justification. The same goes for New Yorkers that are vaccinated and those that are not vaccinated. The City itself created the different classes by creating those mandates.

190) There was a sad time in our history when people of a certain race were not allowed in public places. Are we going back to those days?!

191) The NYC Vaccine Mandates, on its face, improperly grants exemptions for some medical conditions while denying natural immunity-based exemptions.

192) For all of these reasons, the NYC Vaccine Mandates on their face are causing and will continue to cause irreparable harm and undue hardship to Plaintiff.

COUNT IV: FALSE IMPRISONMENT:

193) Additionally, Plaintiff claims, as he believes that this should be considered false imprisonment. Imprisonment is not only when the person is physically contained. In this case, I am allowed to leave my house, but cannot go into “movie theaters, music or concert venues, adult entertainment, casinos, botanical gardens, commercial event and party venues, museums and galleries, aquariums, zoos, professional sports arenas and indoor stadiums, convention centers and exhibition halls, performing arts theaters, bowling alleys, arcades, indoor play areas, pool and billiard halls, and other recreational game centers, Indoor Food

Services, including indoor portions of food service establishments offering food and drink, including all indoor dining areas of food service establishments that receive letter grades as described in section 81.51 of the Health Code; businesses operating indoor seating areas of food courts; catering food service establishments that provide food indoors on its premises; and any indoor portions of food service establishment that is regulated by the New York State Department of Agriculture and Markets offering food for on-premises indoor consumption, Indoor Gyms and Fitness Settings, including indoor portions of standalone and hotel gyms and fitness centers, gyms and fitness centers in higher education institutions, yoga/Pilates/barre/dance studios, boxing/kickboxing gyms, fitness boot camps, indoor pools, CrossFit or other plyometric boxes, and other facilities used for conducting group fitness classes.” This list is in the Executive Order. It might have been shorter if they listed the places that I am permitted to go into.

194) Prisoners in actual prisons often have access to more than I currently have access to. According to New York Penal Law §135, false imprisonment occurs when an individual unlawfully restrains a person's movement without their consent in a way that restricts their freedom or prevents them from leaving.

195) The direct result of the vaccine requirements to all the above listed public accommodations, limits the Plaintiff from being able to go out to any of so

many places, to a point that his movements are severely limited. There are tens of thousands of locations that fall under the indoor public venue mandate alone.

196) In CITY OF CHICAGO v. MORALES et al. United States Supreme Court (1999), it states the following: We have expressly identified this "right to remove from one place to another according to inclination" as "an attribute of personal liberty" protected by the Constitution. Williams v. Fears, 179 U. S. 270, 274 (1900); see also Papachristou v. Jacksonville, 405 U. S. 156, 164 (1972).[20] 54*54 Indeed, it is apparent that an individual's decision to remain in a public place of his choice is as much a part of his liberty as the freedom of movement inside frontiers that is "a part of our heritage" Kent v. Dulles, 357 U. S. 116, 126 (1958), or the right to move "to whatsoever place one's own inclination may direct" identified in Blackstone's Commentaries. 1 W. Blackstone, Commentaries on the Laws of England 130 (1765).

197) Taking away that freedom, is both a violation of the Plaintiff's liberties, and a form of false imprisonment.

COUNT V: THE NYC VACCINE MANDATES IS CONTRARY TO
FEDERAL STATUTORY LAW

198) Plaintiff reallege and incorporate by reference all the foregoing allegations as though fully set forth herein.

199) **The EUA Statute Renders Defendant’ NYC Vaccine Mandates Invalid.**

200) Defendant’ NYC Vaccine Mandates requires Plaintiff and others similarly situated to receive a vaccine in order to work or go to public venues in New York City, without regard to their natural immunity or the advice of their doctors.

201) Plaintiff and others must also divulge personal medical information to the satisfaction of the City and are threatened with disciplinary action if they decline to comply with these arbitrary mandates.

202) The NYC Vaccine Mandates thus coerces or, at the very least, unduly pressures, Plaintiff and others like them into getting vaccines that FDA approved only for emergency use.

203) The EUA statute mandates informed and voluntary consent. *See John Doe No. 1 v. Rumsfeld*, No. Civ. A. 03-707(EGS), 2005 WL 1124589, *1 (D.D.C. Apr. 6, 2005) (allowing use of anthrax vaccine pursuant to EUA “on a *voluntary* basis”). *See also* 21 U.S.C. § 360bbb3(e)(1)(A)(ii).

204) The EUA statute expressly states that recipients of products approved for use under it be informed of the “option to accept *or refuse* administration”

(emphasis added) and of the “significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown.” *Id.*

205) Since the NYC Vaccine Mandates coerces Plaintiff by making enjoyment of his constitutionally and statutorily protected bodily integrity and informed consent rights contingent upon receiving an experimental vaccine, it cannot be reconciled with the letter or spirit of the EUA statute. *See* 21 U.S.C. § 360bbb-3.

206) The conflict between the NYC Vaccine Mandates and the EUA statute is particularly stark given that the statute’s informed consent language requires that recipients be given the “option to refuse” the EUA product. That statutory condition is at odds with these mandates, effectively forcing Plaintiff to sustain significant injury to his career potential and restriction of movement, if he refuses the vaccine.

207) The FDA’s Approval of the Comirnaty Vaccine Does Not Save the NYC Vaccine Mandates from Invalidity.

208) The other defense that I anticipate Defendant mounting is premised on the FDA’s approval of the Comirnaty Vaccine.

209) That the Comirnaty Vaccine has received full FDA approval does not foreclose the argument presented in this count that a federal statute trumps the NYC Vaccine Mandates. That is because this approval does not extend to the BioNTech

Vaccine, which is actually available. Indeed, even Pfizer acknowledges that the two vaccines are “legally distinct.”

210) The two Pfizer vaccines are legally distinct and include differences. For example, the two vaccines have a different total number of ingredients: Comirnaty has eleven (11) ingredients while Pfizer-BioNTech has just ten (10) ingredients. FDA, Vaccine Information Fact Sheet for Recipients and Caregivers about COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) (Aug. 23, 2021), *available at* <https://www.fda.gov/media/151733/download> (last viewed Nov. 1, 2021).

211) The approval announcement posted on the FDA’s website reads, “On August 23, 2021, the FDA approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty, for the prevention of COVID-19 disease in individuals 16 years of age and older.” *Id.*

212) While Pfizer’s Comirnaty approval letter states that its two vaccines share the same formulation, the FDA concedes that “the products are legally distinct with certain differences . . .” *Id.* (emphasis added).

213) To date, no entity has revealed, nor has Plaintiff been able to obtain, any evidence indicating what those “certain differences” may be. Despite this, the FDA asserts that the two formulations can be used interchangeably.

214) For example, in the FDA’s fact sheet for recipients and caregivers,, it reads, “The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA authorized PfizerBioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.” *Id.*

215) In a press release announcing Pfizer’s collaboration with Brazil’s Eurofarma to manufacture COVID-19 vaccine doses, Pfizer wrote, “COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech” and “PfizerBioNTech COVID-19 Vaccine has received EUA from FDA.” The press release continued, stating, “This emergency use of the product has not been approved or licensed by FDA, but has been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) . . .” *Pfizer, Pfizer and BioNTech Announce Collaboration with Brazil’s Eurofarma to Manufacture COVID-19 Vaccine Doses for Latin America* (Aug. 26, 2021), available at <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontechannounce-collaboration-brazils> (last visited Nov. 3, 2021).

216) Then, in a September 6, 2021, press release announcing a submittal to a request by the European Medicines Agency (EMA) to update its Conditional Marketing Authorization (CMA) for a booster dose, BioNTech–Pfizer’s co-partner in the production of the Pfizer-BioNTech COVID-19 vaccine—clearly states, “The Pfizer-BioNTech COVID-19 vaccine has not been approved or licensed by [FDA]” but has been authorized under an EUA. Press Release, *Pfizer and BioNTech Submit a Variation to EMA with the Data in Support of a Booster Dose of COMIRNATY®*, *BIONTECH* (Sept. 6, 2021), available at <https://investors.biontech.de/node/10581/pdf> (last visited Nov. 3, 2021). *See Doe v. Austin*, No. 3:21-cv-1211-AW-HTC (S.D. Florida, Nov. 12, 2021), fn. 5.

217) The claim that the two vaccines are interchangeable comes from a Guidance document, which does not carry force of law. *See Christensen v. Harris County*, 529 U.S. 576, 587-88 (2000) (“Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference.”); *Appalachian Power v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (guidance documents that agencies treat as *de facto* law are void because they did not run the notice-and-comment gauntlet) (setting aside an agency guidance document in its entirety); *see also Texas v. EEOC*, 933 F.3d 433, 443 (5th Cir. 2019) (applying *Appalachian Power*’s analysis to an EEOC guidance document the court

went on to invalidate); *Gate Guard Servs. L.P. v. Solis*, Civ. A. No. V-10-91, 2011 SL 2784447, *5 (S.D. Tex. July 12, 2011) (following *Appalachian Power* and rejecting a Department of Labor defense to a challenge to statements by its regulators at “final conferences” were merely informal and preliminary verbal opinions).

218) The FDA cannot convert a legally distinct product that is available (the BioNTech vaccine) into a fully approved vaccine (Comirnaty) that is not yet widely available. The FDA, via a mere guidance document, is improperly trying to establish equivalence between what are two legally distinct vaccines. That is improper as a general matter of administrative law. It is yet more improper since it is a maneuver conducted to override federal statutory rights to informed medical consent.

219) Defendant cannot be permitted to rely on mere FDA-issued guidance documents, especially not where doing so would vitiate clear statutory rights.

220) Referring to the Comirnaty Vaccine, Pfizer has admitted that there “is not sufficient approved vaccine available for distribution to this population in its entirety at the time of the reissuance of this EUA.”

221) Since the Comirnaty Vaccine, being the only FDA-approved vaccine, is not widely available, and certainly is not available to all members of the population, nor is the legally distinct BioNTech, the EUA statute’s sphere of operation continues to apply to override the NYC Vaccine Mandates.

222) The NYC Vaccine Mandates accept many vaccines that have not received full FDA approval. While the one that is approved is not yet available, everyone in compliance, most certainly was injected with a vaccine only authorized for emergency use.

THE NYC VACCINE MANDATES ARE ARBITRARY AND CAPRICIOUS AND SHOULD BE STRUCK DOWN:

223) No less than current Pfizer Board Member and former FDA Commissioner Dr. Scott Gottlieb³ has acknowledged that natural immunity is an important part of the problems related to fashioning a proper public policy to address COVID-19. “It’s fair to conclude ...” “[t]he balance of the evidence demonstrates that natural immunity confers a durable protection.” Gottlieb Interview, Squawkbox CNBC (Aug. 30, 2021) *available at* <https://twitter.com/i/status/1432321613467357187> (last visited Oct. 29, 2021) (on the video, Dr. Gottlieb calls natural immunity not just “durable” but “robust”). Most importantly, Dr. Gottlieb told CNBC that it cannot be disputed that officials “should start assimilating [natural immunity] into our policy discussions.” *Id.* Yet there is no evidence that the City of New York assimilated naturally acquired immunity into

³ Dr. Gottlieb received his medical degree from the Icahn School of Medicine at Mount Sinai and he completed his residency at the Mount Sinai Hospital.

the policy ordered in the NYC Vaccine Mandates. Accordingly, the NYC Vaccine Mandates are arbitrary and capricious.

224) Indeed, it is *inherently* arbitrary and capricious to include on a menu of coercive vaccine options vaccines not approved for use in the United States. In addition, it is arbitrary and capricious to set these aggressive deadlines for compliance with the NYC Vaccine Mandates knowing fully that they would precede the issuance of either regulations and other specific policies precisely so as (a) to coerce people into rushing to get a COVID-19 vaccine before such regulations or more detailed guidance providing true fair notice could be put in place; and (b) to frustrate the ability of those wanting to seek judicial review to avoid taking a vaccine. Even now the process, criteria, and methodology utilized for assessing exemptions and adverse employment actions are opaque.

225) Furthermore, the fact that there is no ability, under any set of conditions, to apply for an exemption to the mandate *even if one can demonstrate the most robust and durable natural immunity levels* reveals that the NYC Vaccine Mandates rest on reasoning so implausible that it cannot be ascribed to a valid difference in expert opinion or to special agency expertise.

226) Administrative ease, the most generous explanation for the mandates' failure to recognize naturally acquired immunity, should not override an individual's

right to refuse an unwanted violation of bodily integrity and to decline an unnecessary medical intervention.

227) Plaintiff has suffered and will continue to suffer harm from Defendant's conduct. There is no adequate remedy at law, as there are no damages that could compensate Plaintiff for the deprivation of his constitutional and statutory rights, nor for the consequences of being forced to take a vaccine. Plaintiff will suffer irreparable harm unless this Court enjoins Defendant from enforcing the NYC Vaccine Mandates.

RELIEF REQUESTED

WHEREFORE, Plaintiff respectfully requests that the Court find the Defendant have committed the violations alleged and described above, and issue in response the following:

A. A declaratory judgment that the NYC Vaccine Mandates infringe upon Plaintiff's constitutionally protected rights to protect his bodily integrity and autonomy and to refuse unnecessary medical treatment.

B. A declaratory judgment that the NYC Vaccine Mandates represent an unconstitutional condition, especially in light of a set of explicit and implicit procedures that violate procedural due process under the Due Process Clause of the Fourteenth Amendment.

C. A declaratory judgment that the NYC Vaccine Mandates represent a violation of the equal protection rights of Plaintiff.

D. A declaratory judgment that the NYC Vaccine Mandates are invalid under the EUA statute because the City of New York fails to provide for the informed-consent right to refuse a COVID-19 vaccine;

E. A declaratory judgment holding that the NYC Vaccine Mandates are arbitrary and capricious;

F. An injunction enjoining the implementation of the NYC Vaccine Mandates as *ultra vires* under the Constitution and statutory law.

G. Temporary, preliminary and permanent injunctive relief restraining and enjoining Defendant, their agents, servants, employees, attorneys, and all persons in active concert or participation with them, and each of them, from enforcing coercive or otherwise pressuring policies or conditions on Plaintiff to get him to take a COVID-19 vaccine similar to those in the NYC Vaccine Mandates;

H. Plaintiff seek compensatory damages of to be determined and calculated during the discovery period, and proven at trial.

I. Grant such other and further relief as the Court may deem just and proper under the circumstances.

PLAINTIFF'S CERTIFICATION AND WARNINGS

By signing below, I certify to the best of my knowledge, information, and belief that: (1) the complaint is not being presented for an improper purpose (such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation); (2) the claims are supported by existing law or by a nonfrivolous argument to change existing law; (3) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery; and (4) the complaint otherwise complies with the requirements of Federal Rule of Civil Procedure 11.

I agree to notify the Clerk's Office in writing of any changes to my mailing address. I understand that my failure to keep a current address on file with the Clerk's Office may result in the dismissal of my case.

Respectfully submitted this 12th day of January 2022.

s/Aaron Abadi

Aaron Abadi, plaintiff
82 Nassau Street Apt 140
New York, NY 10038
Telephone: 516-639-4100
E-Mail: abadi.rne@gmail.com

CERTIFICATE OF SERVICE

I hereby certify that on January 12, 2022, I filed this Amended Complaint through the pro se office including all accompanying exhibits which will then be immediately filed online on the CM/ECF electronic filing system, and the Defendants Attorney will have immediately received a copy, as the Defendant requested to receive filings electronically:

Assistant Corporation Counsel
Jasmine Paul
GEORGIA M. PESTANA
Corporation Counsel of
the City of New York
Attorney for Defendant
100 Church St., Rm. 5-182
New York, New York 10007
Email: jpaul@law.nyc.gov
Tel: (212) 356-2192

s/Aaron Abadi
Aaron Abadi, plaintiff

Skip Main Navigation

Menu

The Official Website of the City of New York

Exhibit A

—

—

Text Size

Select Language ▼

Powered by Google Translate

Search

Search

Search

Secondary Navigation

MayorFirst LadyNewsOfficials

Emergency Executive Order 225

August 16, 2021

Key to NYC: Requiring COVID-19 Vaccination for Indoor Entertainment, Recreation, Dining and Fitness Settings

Download Emergency Executive Order 225

WHEREAS, the COVID-19 pandemic has severely impacted New York City and its economy, and is addressed effectively only by joint action of the City, State, and Federal governments;

WHEREAS, the state of emergency to address the threat and impacts of COVID-19 in the City of New York first declared in Emergency Executive Order No. 98, and extended most recently by Emergency Executive Order No. 220, remains in effect;

WHEREAS, this Order is necessary because of the propensity of the virus to spread person-to-person, and also because the actions taken to prevent such spread have led to property loss and damage;

WHEREAS, the U.S. Centers for Disease Control (“CDC”) reports that new variants of COVID-19, classified as “variants of concern,” are present in the United States;

WHEREAS, some of these new variants currently account for the majority of COVID-19 cases sequenced in New York City and are much more transmissible than earlier variants;

WHEREAS, the CDC has stated that vaccination is the most effective tool to mitigate the spread of COVID-19 and protect against severe illness;

WHEREAS, the CDC has also stated that vaccination benefits both vaccine recipients and those with whom they come into contact, including individuals who are ineligible for the vaccine due to age, health or other conditions;

WHEREAS, the recent appearance in the City of the highly transmissible Delta variant of COVID-19 has substantially increased the risk of infection;

WHEREAS, indoor entertainment, recreation, dining and fitness settings generally involve groups of unassociated people interacting for a substantial period of time and requiring vaccination for all individuals in these areas, including workers, will protect the public health, promote public safety, and save the lives of not just those vaccinated individuals but the public at large;

WHEREAS, 56% of City residents are fully vaccinated and 62% of residents have received at least one dose, and mandating vaccinations at the types of establishments that residents frequent will incentivize vaccinations, increasing the City's vaccination rates and saving lives; and

WHEREAS, a study by Yale University demonstrated that the City's vaccination campaign was estimated to have prevented about 250,000 COVID-19 cases, 44,000 hospitalizations and 8,300 deaths from COVID-19 infection since the start of vaccination through July 1, 2021, and the City believes the number of prevented cases, hospitalizations and death has risen since then; and that between January 1, 2021, and June 15, 2021, over 98% of hospitalizations and deaths from COVID-19 infection involved those who were not fully vaccinated;

NOW, THEREFORE, pursuant to the powers vested in me by the laws of the State of New York and the City of New York, including but not limited to the New York Executive Law, the New York City Charter and the Administrative Code of the City of New York, and the common law authority to protect the public in the event of an emergency:

Section 1. I hereby order that a covered entity shall not permit a patron, full- or part-time employee, intern, volunteer, or contractor to enter a covered premises without displaying proof of vaccination and identification bearing the same identifying information as the proof of vaccination.

§ 2. I hereby order that the following individuals are exempted from this Order, and therefore may enter a covered premises without displaying proof of vaccination, provided that such individuals wear a face mask at all times they are unable to maintain six (6) feet of distance from other individuals inside the covered premises:

- a. Individuals entering for a quick and limited purpose (for example, using the restroom, placing or picking up an order or service, changing clothes in a locker room, or performing necessary repairs);
- b. A nonresident performing artist not regularly employed by the covered entity while they are in a covered premises for purposes of performing;
- c. A nonresident professional athlete/sports team who enters a covered premises as part of their regular employment for purposes of competing; and
- d. A nonresident individual accompanying a performing artist or professional athlete/sports team into a covered premises as part of their regular employment so long as the performing artist or professional athlete/sports team are performing or competing in the covered premises.

§ 3. I hereby direct each covered entity to develop and keep a written record describing the covered entity's protocol for implementing and enforcing the requirements of this Order. Such written record shall be available for inspection upon a request of a City official as allowed by law.

§ 4. I hereby direct each covered entity to post a sign in a conspicuous place that is viewable by prospective patrons prior to entering the establishment. The sign must alert patrons to the vaccination

requirement in this Order and inform them that employees and patrons are required to be vaccinated. The Department for Health and Mental Hygiene ("DOHMH") shall determine the text of such sign and provide a template on its website that a covered entity may use. A covered entity may use the sign available online at nyc.gov/keytoNYC, or use its own sign provided its sign must be no smaller than 8.5 inches by 11 inches, with text provided by DOHMH in at least 14-point font.

§ 5. For the purposes of this Order:

- a. "Contractor" means the owner and/or employees of any business that a covered entity has hired to perform work within a covered premise, except that it shall not include nonresident owners and/or employees.
- b. "Covered entity" means any entity that operates one or more covered premises, except that it shall not include pre-kindergarten through grade twelve (12) public and non-public schools and programs, child care programs, senior centers, community centers, or as otherwise indicated by this Order.
- c. "Covered premises" means any location, except a location in a residential or office building the use of which is limited to residents, owners, or tenants of that building, that is used for the following purposes:
 - i. **Indoor Entertainment and Recreational Settings**, including indoor portions of the following locations, regardless of the activity at such locations: movie theaters, music or concert venues, adult entertainment, casinos, botanical gardens, commercial event and party venues, museums and galleries, aquariums, zoos, professional sports arenas and indoor stadiums, convention centers and exhibition halls, performing arts theaters, bowling alleys, arcades, indoor play areas, pool and billiard halls, and other recreational game centers;
 - ii. **Indoor Food Services**, including indoor portions of food service establishments offering food and drink, including all indoor dining areas of food service establishments that receive letter grades as described in section 81.51 of the Health Code; businesses operating indoor seating areas of food courts; catering food service establishments that provide food indoors on its premises; and any indoor portions of food service establishment that is regulated by the New York State Department of Agriculture and Markets offering food for on-premises indoor consumption. The requirements of this Order shall not apply to any food service establishment offering food and/or drink exclusively for off-premises or outdoor consumption, or to a food service establishment providing charitable food services such as soup kitchens;
 - iii. **Indoor Gyms and Fitness Settings**, including indoor portions of standalone and hotel gyms and fitness centers, gyms and fitness centers in higher education institutions, yoga/Pilates/barre/dance studios, boxing/kickboxing gyms, fitness boot camps, indoor pools, CrossFit or other plyometric boxes, and other facilities used for conducting group fitness classes.
- d. "Indoor portion" means any part of a covered premises with a roof or overhang that is enclosed by at least three walls, except that the following will not be considered an indoor portion: (1) a structure on the sidewalk or roadway if it is entirely open on the side facing the sidewalk; and (2) an outdoor dining structure for individual parties, such as a plastic dome, if it has adequate ventilation to allow for air circulation.

- e. “Nonresident” means any individual who is not a resident of New York City.
- f. “Patron” means any individual 12 years of age or older who patronizes, enters, attends an event, or purchases goods or services within a covered premise.
- g. “Identification” means an official document bearing the name of the individual and a photo or date of birth. Examples of acceptable identification include but are not limited to: driver’s license, non-driver government ID card, IDNYC, passport, and school ID card.
- h. h. “Proof of vaccination” means proof of receipt of at least one dose of a COVID-19 vaccine authorized for emergency use or licensed for use by the U.S. Food and Drug Administration or authorized for emergency use by the World Health Organization. Such proof may be established by:
 - i. A CDC COVID-19 Vaccination Record Card or an official immunization record from the jurisdiction, state, or country where the vaccine was administered or a digital or physical photo of such a card or record, reflecting the person’s name, vaccine brand, and date administered; or
 - ii. A New York City COVID Safe Pass (available to download on Apple and Android smartphone devices); or
 - iii. A New York State Excelsior Pass.

§ 6. I hereby direct that each instance that a covered entity fails to check an individual’s vaccination status shall constitute a separate violation of this Order.

§ 7. I hereby direct the City’s Commission on Human Rights to develop guidance to assist covered entities in complying with this Order in an equitable manner consistent with applicable provisions of the New York City Human Rights Law.

§ 8. I hereby direct, in accordance with Executive Law § 25, that staff from any agency as may hereafter be designated by the DOHMH Commissioner shall enforce the directives set forth in this Order.

§ 9. I hereby direct that any person or entity who is determined to have violated this Order shall be subject to a fine, penalty and forfeiture of not less than \$1,000. If the person or entity is determined to have committed a subsequent violation of this Order within twelve months of the initial violation for which a penalty was assessed, such person or entity shall be subject to a fine, penalty and forfeiture of not less than \$2,000. For every violation thereafter, such person or entity shall be subject to a fine, penalty and forfeiture of not less than \$5,000 if the person or entity committed the violation within twelve months of the violation for which the second penalty was assessed. This Order may be enforced pursuant to sections 3.05, 3.07, and/or 3.11 of the Health Code and sections 558 and 562 of the Charter. I hereby suspend Appendix 7-A of Chapter 7 of the Rules of the City of New York to the extent it would limit a violation of this Order to be punished with a standard penalty of \$1,000 or a default penalty of \$2,000.

§ 10. Covered entities shall comply with further guidelines issued by DOHMH to further the intent of this Order and increase the number of vaccinated individuals in the City.

§ 11. This Emergency Executive Order shall take effect on August 17, 2021, except for section 9 of this Order, which shall take effect on September 13, 2021.

Bill de Blasio,
MAYOR

Skip Main Navigation

Menu

The Official Website of the City of New York

—

Exhibit B

—

Text Size

Select Language ▼

Powered by Google Translate

Search

Search

Search

Secondary Navigation

MayorFirst LadyNewsOfficials

Executive Order 78

August 31, 2021

Mandatory Vaccination or Test Requirement for City Employees and Covered Employees of City Contractors

Download Executive Order 78

WHEREAS, the COVID-19 pandemic poses a danger to the health and safety of the City of New York and its residents;

WHEREAS, the U.S. Centers for Disease Control (“CDC”) reports that new variants of COVID-19, identified as “variants of concern,” have emerged in the United States, and some of these new variants, which currently account for the majority of COVID-19 cases sequenced in New York City, are more transmissible;

WHEREAS, the CDC has stated that vaccination is an effective tool to prevent the spread of COVID-19 and benefits both vaccine recipients and those they come into contact with, including persons who for reasons of age, health, or other conditions cannot themselves be vaccinated;

WHEREAS, the City and its contractors provide services to all New Yorkers that are critical to the health, safety, and well-being of City residents, and should take reasonable measures to reduce the transmission of COVID-19 when providing such services;

WHEREAS, a study by Yale University demonstrated that the New York City Department of Health’s vaccination campaign was estimated to have prevented about 250,000 COVID-19 cases, 44,000 hospitalizations and 8,300 deaths from COVID-19 infection since the start of vaccination through July 1, 2021, and the Department believes the number of prevented cases, hospitalizations and death has risen since then; and that between January 1, 2021, and June 15, 2021, over 98% of hospitalizations and deaths from COVID-19 infection involved those who were not fully vaccinated;

WHEREAS, it is essential that the City promote the best health and safety practices recognized in light of current scientific understanding of the conditions under which COVID-19 can spread; and

NOW, THEREFORE, by the power vested in me as the Mayor of the City of New York, it is hereby ordered:

Section 1. City employees must either:

- a. Provide the City agency or office where they work with proof of full vaccination by September 13, 2021, or
- b. Beginning September 13, 2021, and on a weekly basis thereafter until the employee submits proof of full vaccination, provide the City agency or office where they work with proof of a negative COVID-19 PCR diagnostic test (not an antibody test).

Nothing in this Order shall preclude a City agency from requiring an employee who has been vaccinated to be tested for COVID-19 or preclude a City agency from requiring employees to be tested more frequently than once a week.

§ 2. Any City employee who does not comply with this Order may be subject to disciplinary action.

§ 3. All City agencies must take all necessary actions to require their contractors to require their covered employees to either:

- a. Provide their employer with proof of full vaccination by September 13, 2021, or
- b. Beginning September 13, 2021, and on a weekly basis thereafter until the employee submits proof of full vaccination, provide their employer with proof of a negative COVID-19 PCR diagnostic test (not an antibody test).

All such contractors shall submit a certification to their contracting agency confirming that they are requiring their covered employees to provide such proof. If contractors are non-compliant, the contracting City agencies may exercise any rights they may have under their contract.

§ 4. For purposes of this Order:

- a. The term “full vaccination” means at least two weeks have passed after a person received a single-dose of an FDA- or WHO- approved COVID-19 vaccine or the second dose of an FDA- or WHO- approved two-dose COVID-19 vaccine except that, for the purposes of this Order, a City employee or covered employee of a contractor who provides documentation of having received one dose of any COVID-19 vaccine before September 13, 2021 will be considered fully vaccinated even though two weeks have not passed since their final dose, so long as, if such City employee or covered employee of a contractor received a two-dose vaccine, the employee provides documentation that the second dose has been administered before October 28, 2021.
- b. The term “contract” means a contract awarded by the City, and any subcontract under such a contract, for work: (i) to be performed within the City of New York; and (ii) where employees can be expected to physically interact with City employees or members of the public in the course of performing work under the contract.
- c. The term “contractor” means a person or entity that has a City contract, including the subcontracts described in the definition of “contract.”

- d. The term “covered employee” means a person: (i) employed by a contractor or subcontractor holding a contract; (ii) whose salary is paid in whole or in part from funds provided under a City contract; and (iii) who performs any part of the work under the contract within the City of New York. However, a person whose work under the contract does not include physical interaction with City employees or members of the public shall not be deemed to be a covered employee.
- e. The term “City employee” means a full or part-time employee, intern, or volunteer of a City agency.

§ 5. Each City agency shall send each of its contractors notice that the Mayor has directed contractors to comply with the requirement of section 3 of this Order and request a response from each such contractor, as soon as possible, with regard to the contractor’s intent to follow this Order.

§ 6. This Order shall take effect immediately. Nothing in this Order shall affect the enforcement of other orders issued by the Mayor, the Commissioner of Citywide Administrative Services, the Commissioner of Health and Mental Hygiene, or the Board of Health.

Bill de Blasio,
MAYOR

EXHIBIT 1

**ORDER OF THE COMMISSIONER
OF HEALTH AND MENTAL HYGIENE
TO REQUIRE COVID-19 VACCINATION IN THE WORKPLACE**

WHEREAS, on March 12, 2020, Mayor Bill de Blasio issued Emergency Executive Order No. 98 declaring a state of emergency in the City to address the threat posed by COVID-19 to the health and welfare of City residents, and such Order remains in effect; and

WHEREAS, on March 25, 2020, the New York City Commissioner of Health and Mental Hygiene declared the existence of a public health emergency within the City to address the continuing threat posed by COVID-19 to the health and welfare of City residents, and such declaration and public health emergency continue to be in effect; and

WHEREAS, the COVID-19 virus continues to spread and mutate, and on November 26, 2021, the World Health Organization (“WHO”) declared a new variant of COVID-19, named Omicron, a variant of concern and preliminary evidence suggests an increased risk of reinfection and spread across the world, including to the United States; and

WHEREAS, on November 26, 2021, New York State Governor Kathy Hochul issued Executive Order No. 11 to address new emerging threats across the State posed by COVID-19, finding that New York is experiencing COVID-19 transmission at rates the State has not seen since April 2020 and that the rate of new COVID-19 hospital admissions has been increasing over the past month to over 300 new admissions a day; and

WHEREAS, COVID-19 spreads when an infected person exhales the virus and these are breathed in by other people or land on their eyes, noses, or mouth, with people closer than 6 feet from the infected person most likely to get infected, making the risk of COVID-19 transmission greater in workplace settings because of close proximity to others and the sharing of office space and facilities such as restrooms, elevators, lobbies, meeting and break rooms, and other common areas; and

WHEREAS, the WHO and the U.S. Centers for Disease Control and Prevention (“CDC”) have advised all individuals to take measures to reduce their risk of COVID-19, especially the Delta and Omicron variants, including vaccination, which is an effective tool to prevent the spread of COVID-19 and benefits both vaccine recipients and those they come into contact with, including persons who for reasons of age, health, or other conditions cannot themselves be vaccinated; and

WHEREAS, a study by Yale University demonstrated that the City’s vaccination campaign was estimated to have prevented about 250,000 COVID-19 cases, 44,000 hospitalizations and 8,300 deaths from COVID-19 infection since the start of vaccination through July 1, 2021, and the City believes the number of prevented cases, hospitalizations and death has risen since then; and that between January 1, 2021, and June 15, 2021, over 98% of hospitalizations and deaths from COVID-19 infection involved those who were not fully vaccinated;

WHEREAS, a system of vaccination that requires employers to implement vaccination policies for their employees will potentially save lives, protect public health, and promote public safety; and

WHEREAS, on September 9, 2021, President Biden issued an Executive Order stating that “It is essential that Federal employees take all available steps to protect themselves and avoid spreading COVID-19 to their co-workers and members of the public,” and ordering each federal agency to “implement, to the extent consistent with applicable law, a program to require COVID-19 vaccination for all of its Federal employees, with exceptions only as required by law”; and

WHEREAS, on August 16, 2021, Mayor Bill de Blasio signed Emergency Executive Order No. 225, the “Key to NYC,” which requires the employees, as well as patrons, of establishments providing indoor entertainment, dining, and fitness to show proof of at least one dose of an approved COVID-19 vaccine, and such Order, as reissued in Emergency Executive Order No. 316 on December 13, 2021, is still in effect; and

WHEREAS, on August 24, 2021, I issued an Order requiring that Department of Education employees, contractors, and visitors provide proof of COVID-19 vaccination before entering a DOE building or school setting, and such Order was re-issued on September 12 and 15, 2021, and subsequently amended on September 28, 2021, and such Orders and amendment were ratified by the Board of Health on September 17, 2021 and October 18, 2021; and

WHEREAS, on September 12, 2021, I issued an Order requiring that staff of early childhood programs or services provided under contract with the Department of Education or the Department of Youth and Community Development provide proof of COVID-19 vaccination, and that Order was ratified by the Board of Health on September 17, 2021; and

WHEREAS, on October 20, 2021, I issued an Order requiring that City employees provide proof of vaccination to their agencies or offices by October 29, 2021 or be excluded from their workplace, and on October 31, 2021, I issued a supplemental Order, and both Orders were ratified by the Board of Health on November 1, 2021; and

WHEREAS, on November 17, 2021, I issued an Order requiring COVID-19 vaccinations for staff of child care programs, as defined therein, and in early intervention programs, and such Order was ratified by the Board of Health on November 19, 2021; and

WHEREAS, on December 2, 2021, I issued an Order requiring COVID-19 vaccinations for all nonpublic school staff and volunteers; and

WHEREAS, pursuant to Section 558 of the New York City Charter (the “Charter”), the Board of Health may embrace in the Health Code all matters and subjects to which the power and authority of the Department of Health and Mental Hygiene (“the Department”) extends; and

WHEREAS, pursuant to Section 556 of the Charter and Section 3.01(c) of the Health Code, the Department is authorized to supervise the control of communicable diseases and

conditions hazardous to life and health and take such actions as may be necessary to assure the maintenance and protection of public health; and

WHEREAS, Section 17-104 of the New York City Administrative Code (“Administrative Code”) directs the Department to adopt prompt and effective measures to prevent the communication of infectious diseases such as COVID-19, and in accordance with Section 17-109(b) of Administrative Code, the Department may adopt vaccination measures to effectively prevent the spread of communicable diseases; and

WHEREAS, pursuant to Section 3.01(d) of the Health Code, I am authorized to issue orders and take actions that I deem necessary for the health and safety of the City and its residents when urgent public health action is needed to protect the public health against an existing threat and a public health emergency has been declared pursuant to such section; and

NOW THEREFORE, I, Dave A. Chokshi, MD, MSc, Commissioner of the Department of Health and Mental Hygiene, finding that a public health emergency within New York City continues, and that it is necessary for the health and safety of the City and its residents, do hereby exercise the power of the Board of Health to prevent, mitigate, control and abate the current emergency, and hereby order that:

1. Beginning December 27, 2021, workers must provide proof of vaccination against COVID-19 to a covered entity before entering the workplace, and a covered entity must exclude from the workplace any worker who has not provided such proof, except as provided in paragraph 5.
2. Covered entities shall verify workers’ proof of vaccination. Covered entities shall:
 - a. maintain a copy of each worker’s proof of vaccination and, if applicable, a record of reasonable accommodation(s) as described in (b)(iv); *OR*
 - b. maintain a record of such proof of vaccination, provided that such record shall include:
 - i. the worker’s name; and
 - ii. whether the person is fully vaccinated; and
 - iii. for a worker who submits proof of the first dose of a two-dose vaccine, the date by which proof of the second dose must be provided, which must be no later than 45 days after the proof of first dose was submitted; and
 - iv. for a worker who does not submit proof of COVID-19 vaccination because of a reasonable accommodation, the record must indicate that such accommodation was provided, and the covered entity must separately maintain records stating the basis for such accommodation and any supporting documentation provided by such worker; *OR*
 - c. check the proof of vaccination before allowing a worker to enter the workplace and maintain a record of the verification.

For a non-employee worker, such as a contractor, a covered entity may request that the worker's employer confirm the proof of vaccination in lieu of maintaining the above records. A covered entity shall maintain a record of such request and confirmation.

Records created or maintained pursuant to this section shall be treated as confidential.

A covered entity shall, upon request by a City agency, make available for inspection records required to be maintained by this section, consistent with applicable law.

3. No later than December 27, 2021, a covered entity shall affirm on a form provided by the Department compliance with the requirements of paragraph 2 of this Order and post the affirmation in a conspicuous location.
4. For purposes of this Order:
 - a. "Covered entity" means:
 - i. a non-governmental entity that employs more than one worker in New York City or maintains a workplace in New York City; or
 - ii. a self-employed individual or a sole practitioner who works at a workplace or interacts with workers or the public in the course of their business.
 - b. "Fully vaccinated" means at least two weeks have passed after an individual received a single dose of a COVID-19 vaccine that requires only one dose, or the second dose of a two-dose series of a COVID-19 vaccine approved or authorized for use by the Food and Drug Administration or World Health Organization, or any other circumstance defined by the Department in its guidance associated with this Order.
 - c. "Proof of vaccination" means one of the following documents demonstrating that an individual has (1) been fully vaccinated against COVID-19; (2) received one dose of a single-dose COVID-19 vaccine; or (3) received the first dose of a two-dose COVID-19 vaccine, provided that a worker providing proof of only such first dose provides proof of receiving the second dose of that vaccine within 45 days after receiving the first dose:
 - i. A CDC COVID-19 Vaccination Record Card or other official immunization record from the jurisdiction, city, state, or country where the vaccine was administered, or from a healthcare provider or other approved immunizer who administered the vaccine, that provides the person's name, vaccine brand, and date of administration. A digital photo or photocopy of such record is also acceptable.
 - ii. New York City COVID Safe App showing a vaccination record;
 - iii. A valid New York State Excelsior Pass/Excelsior Pass Plus;
 - iv. CLEAR Health Pass; or

v. Any other method specified by the Commissioner as sufficient to demonstrate proof of vaccination.

d. “Worker” means an individual who works in-person in New York City at a workplace. Worker includes a full- or part-time staff member, employer, employee, intern, volunteer or contractor of a covered entity, as well as a self-employed individual or a sole practitioner.

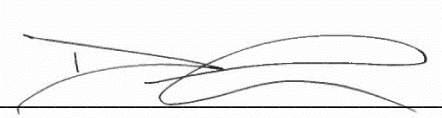
Worker does not include:

- i. an individual who works from their own home and whose employment does not involve interacting in-person with co-workers or members of the public;
- ii. an individual who enters the workplace for a quick and limited purpose; or
- iii. non-City residents who are performing artists, college or professional athletes, or individuals accompanying such performing artists or college or professional athletes who do not have to display proof of vaccination pursuant to the Key to NYC program, Emergency Executive Order No. 316 and successor Orders.

e. “Workplace” means any location, including a vehicle, where work is performed in the presence of another worker or member of the public.

- 5. Nothing in this Order shall be construed to prohibit reasonable accommodations for medical or religious reasons.
- 6. This Order shall not apply to covered entities or individuals who are already subject to another Order of the Commissioner of the Department, Board of Health, the Mayor, or a State or federal entity that is in effect and requires them to maintain or provide proof of full vaccination or to individuals who have been granted a reasonable accommodation pursuant to such requirement.
- 7. This Order shall take effect immediately, and remain in effect until rescinded, subject to the authority of the Board of Health to continue, rescind, alter, or modify this Order pursuant to Section 3.01(d) of the Health Code.

Dated: December 13, 2021



Dave A. Chokshi, MD, MSc
Commissioner

Name: Aaron Abadi | DOB: [REDACTED] | MRN: 9141633 | PCP: Yelena Karasina, MD

Letter Details

Exhibit D



Yelena Karasina, MD
NYU LANGONE AMBULATORY CARE WEST SIDE

355 WEST 52ND ST
NEW YORK NY 10019-6239
Phone: 646-754-2100
Fax: 646-754-2148

December 3, 2020

Patient: **Mr. Aaron Abadi**
Date of Birth: [REDACTED]
Date of Visit: **12/3/2020**

To Whom it May Concern:

Mr. Aaron Abadi is suffering from extreme sensitivity to touch, mostly in the area of his head. For this reason he is unable to wear face mask or face shield, and should not be required to do so.
He has already recovered from COVID, and is not contagious.

Sincerely,

Yelena Karasina, MD

This letter was initially viewed by Aaron Abadi at 12/7/2020 9:41 AM.

MyChart® licensed from Epic Systems Corporation © 1999 - 2021

Secure Message

Exhibit E

Sent Date: 09/05/2021 01:13 AM
From: Department of Labor
To: AARON ABADI
Priority: NORMAL
Subject: End of Unemployment Benefits

Dear AARON ABADI:

This letter is proof that you have received all regular Unemployment Insurance benefits available on your current claim. This means you have received the maximum 26 weeks (104 effective days) of benefits on your claim with a benefit year ending 03/14/2021.

You cannot receive any more regular Unemployment Insurance benefits on this claim. Please note that there are no extensions of Unemployment Insurance benefits available beyond 26 weeks.

We encourage you to continue working with your local New York State Career Center to find a job. To find your closest Career Center, go to <http://labor.ny.gov/career-center-locator/> [<http://labor.ny.gov/career-center-locator/>] or call our Contact Center at 1-888-4 NYSDOL (1-888-469-7365). Services offered include:

- * Help with resume writing and interviewing skills;
- * Career advice and guidance;
- * Skills assessments to help determine jobs you might be suited for;
- * Job-hunting workshops;
- * Information about jobs available in a particular area or industry (labor market information);
- * Job referrals and;
- * Information about training opportunities and referrals to training when appropriate.

Career Services are available at no charge to you.

We also recognize that the ending of your Unemployment Insurance benefits may create a serious financial hardship for you and your family. Please go to www.mybenefits.ny.gov [<http://www.mybenefits.ny.gov>] to see what programs may be available to help you with food, shelter, health insurance and other needs.

For the Commissioner of Labor,

By: Unemployment Insurance Division

EXHIBIT F

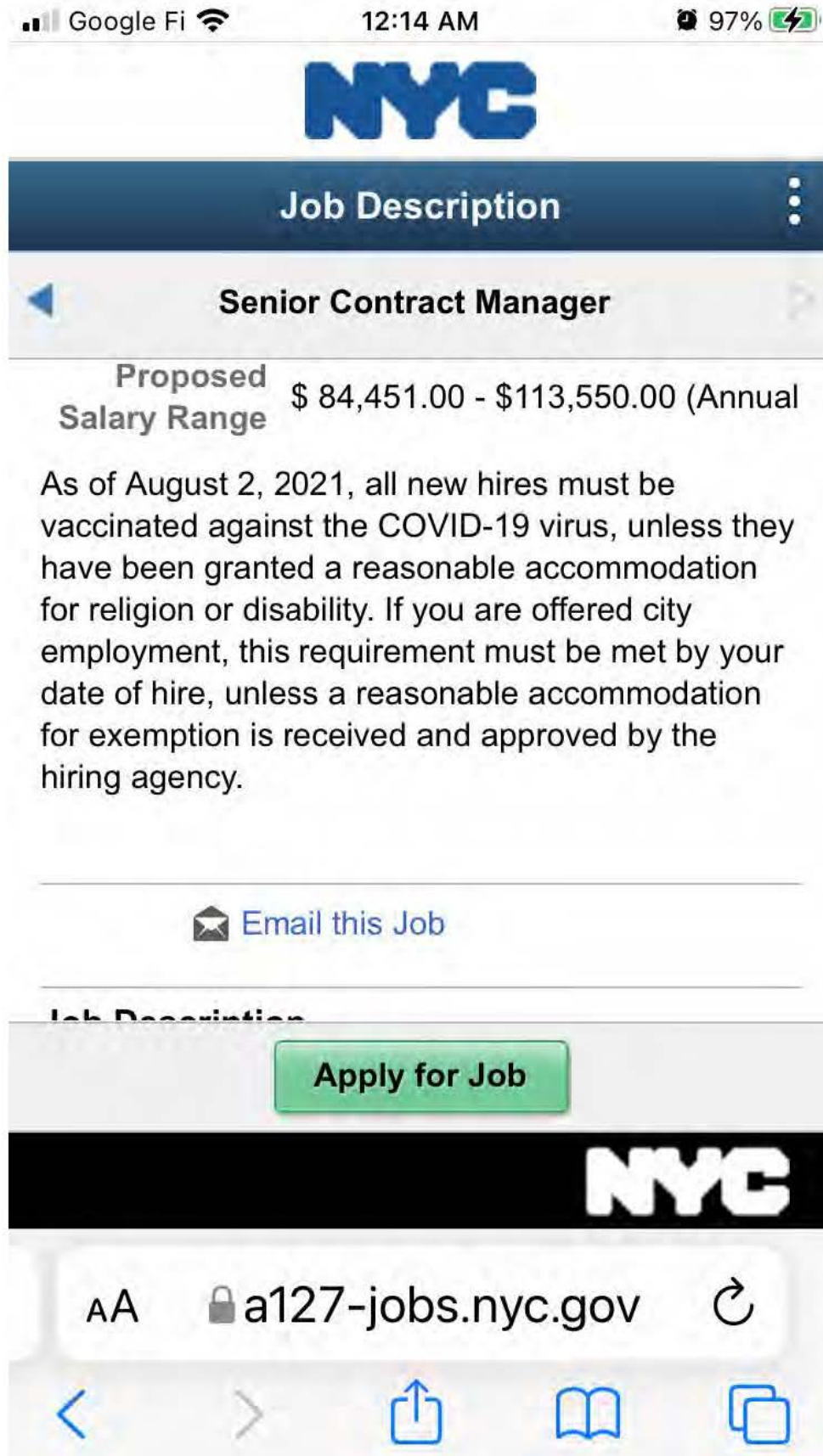


EXHIBIT G

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

ERIC MCARTHUR and JENNY
MCARTHUR,
Proceeding on their own behalf and on
Behalf of their minor child, M.M.,

Plaintiffs,

v.

SCOTT BRABRAND, *et. al.*,

Defendants,

Civil Action No.: _____

Joint Declaration of Dr. Jayanta Bhattacharya and Dr. Martin Kulldorff

We, Drs. Jayanta (“Jay”) Bhattacharya and Martin Kulldorff provide the following Joint Declaration and hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct:

Background

1. Dr. Jay Bhattacharya is a Professor of Medicine at Stanford University and a research associate at the National Bureau of Economic Research. He is also Director of Stanford’s Center for Demography and Economics of Health and Aging. He holds an M.D. and Ph.D. from Stanford University. He has published 152 scholarly articles in peer-reviewed journals in the fields of medicine, economics, health policy, epidemiology, statistics, law, and public health, among others. His research has been cited in the peer-reviewed scientific literature more than 11,000 times.

2. Dr. Martin Kulldorff is a Professor of Medicine at Harvard Medical School, and he is a biostatistician and epidemiologist at Brigham and Women's Hospital. He holds a Ph.D. from Cornell University. He is the author of 237 published articles in leading medical, epidemiological, statistics, and science journals, cited over 25,000 times in peer-reviewed scientific journals. Dr. Kulldorff is recognized internationally for his foundational research on the detection and monitoring of disease outbreaks and on the monitoring and evaluation of vaccine safety issues. His epidemiological methods are routinely used by the Centers for Disease Control and Prevention ("CDC"), the Food and Drug Administration ("FDA") and other public health agencies around the world.

3. Both of us have dedicated our professional careers to the analysis of public health data, including infectious disease epidemiology and policy, and the efficacy and safety of medical interventions.

4. We have both studied extensively and commented publicly on the necessity and safety of vaccine requirements for those who have contracted and recovered from COVID-19 (individuals who have "natural immunity"). We are intimately familiar with the emergent scientific and medical literature on this topic and pertinent government policy responses to the issue both in the United States and abroad.

5. Our assessment of vaccine immunity is based on studies related to the efficacy and safety of the three vaccines that have received Emergency Use Authorization ("EUA") from the Food and Drug Administration (FDA) for use in the United States. These include two mRNA technology vaccines (manufactured by Pfizer-BioNTech and Moderna) and an adenovirus vector vaccine technology (manufactured by Johnson & Johnson).

6. Neither of us has received any financial or other compensation to prepare this Declaration. Nor have we ever received any personal or research funding from any pharmaceutical company. In writing this, we are motivated solely by our commitment to public health.

7. Neither of us has an existing doctor-patient relationship with Jeanna Norris.

8. We have been asked to provide our opinion on several matters related to Michigan State University (“MSU” or “University”) vaccine policy for faculty and staff (the “mandatory vaccination” directive), including the following:

- a. Whether, based on the current medical and scientific knowledge, natural immunity is categorically inferior to vaccine immunity to prevent reinfection and transmission of the SARS-CoV-2 virus;
- b. Whether, based on the existing medical and scientific understanding of SARS-CoV-2 transmission and recovery, there is any categorical distinction between natural immunity and vaccine immunity; and
- c. An assessment of the comparative safety to recipients of administering vaccines to those who have natural immunity relative to immunologically naïve recipients with no prior history of COVID infection.

9. Our opinions are summarized in a recent article we published and which we reaffirm here: “[R]ecovered COVID patients have strong, long-lasting protection against severe disease if reinfected, and evidence about protective immunity after natural infection is stronger than the evidence from the vaccines. Hence, it makes no sense to require vaccines for recovered COVID patients. For them, it simply adds a risk, however small.”¹

¹ Martin Kuldorff and Jay Bhattacharya, *The ill-advised push to vaccinate the young*, THEHILL.COM (June 17, 2021), <https://thehill.com/opinion/healthcare/558757-the-ill-advised-push-to-vaccinate-the-young?rl=1>.

Mortality Risk from COVID-19 Infection and Corresponding Marginal Benefit From Vaccination Varies By Orders of Magnitude Based on Age

10. The mortality risk posed by COVID infection is a basic parameter necessary to understand the public health benefits from vaccines. The best evidence on the infection fatality rate from SARS-CoV-2 infection (that is, the fraction of infected people who die due to the infection) comes from seroprevalence studies. The definition of seroprevalence of COVID-19 is the fraction of people within a population who have specific antibodies against SARS-CoV-2 in their bloodstream. Seroprevalence studies provide better evidence on the total number of people who have been infected than do case reports or a positive reverse transcriptase-polymerase chain reaction (RT-PCR) test counts; these both miss infected people who are not identified by the public health authorities or do not volunteer for RT-PCR testing. Because they ignore unreported cases in the denominator, fatality rate estimates based on case reports or positive test counts are substantially biased upwards. According to a meta-analysis (published by the World Health Organization) by Dr. John Ioannidis of every seroprevalence study conducted with a supporting scientific paper (74 estimates from 61 studies and 51 different localities worldwide), the median infection survival rate from COVID-19 infection is 99.77%. For COVID-19 patients under 70, the meta-analysis finds an infection survival rate of 99.95%.² A newly released meta-analysis by scientists independent of Dr. Ioannidis' group reaches qualitatively similar conclusions.³

11. The mortality risk for those infected with SARS-CoV-2 is not the same for all patients. Older patients are at higher risk of death if infected, while younger patients face a

² Ioannidis JPA, *Infection fatality rate of COVID-19 inferred from seroprevalence data*, BULL WORLD HEALTH ORGAN (Jan 1, 2021).

³ Andrew T. Levin, et al., *Assessing the Age Specificity of Infection Fatality Rates for COVID-19: Meta-Analysis & Public Policy Implications*, MEDRXIV (Aug. 14, 2020), <https://bit.ly/3gpIoIV>.

vanishingly small risk.⁴ The same is true for hospitalization risk, which is similarly age-dependent. The best evidence on age-specific infection fatality rates comes again from seroprevalence studies.

12. The CDC's best estimate of the infection fatality ratio for people ages 0-19 years is 0.00002, meaning infected children have a 99.998% infection survivability rate.⁵ The CDC's best estimate of the infection fatality rate for people ages 20-49 years is 0.0005, meaning that young adults have a 99.95% survivability rate. The CDC's best estimate of the infection fatality rate for people age 50-64 years is 0.006, meaning this age group has a 99.4% survivability rate. The CDC's best estimate of the infection fatality rate for people ages 65+ years is .09, meaning seniors have a 91.0% survivability rate.

13. A study of the seroprevalence of COVID-19 in Geneva, Switzerland (published in the *Lancet*)⁶ provides a detailed age breakdown of the infection survival rate in a preprint companion paper⁷: 99.9984% for patients 5 to 9 years old; 99.99968% for patients 10 to 19 years old; 99.991% for patients 20 to 49 years old; 99.86% for patients 50 to 64 years old; and 94.6% for patients above 65 years old.

14. In summary, the mortality risk posed by COVID infection in the young is vanishingly small, while the threat posed to the elderly is orders of magnitude higher. One direct corollary of this point is that the corresponding personal benefit from vaccination, at least as far as mortality risk is concerned, is orders of magnitude lower for the young relative to the elderly.

⁴ Kulldorff M., *COVID-19 Counter Measures Should Be Age-Specific*, LINKEDIN (Apr. 10, 2020), <https://www.linkedin.com/pulse/covid-19-counter-measures-should-age-specific-martin-kulldorff/>.

⁵ Centers for Disease Control and Prevention, *COVID-19 Pandemic Planning Scenarios*, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html>.

⁶ Silvia Stringhini, et al., *Seroprevalence of Anti-SARS-CoV-2 IgG Antibodies in Geneva, Switzerland (SEROCoV-POP): A Population Based Study*, THE LANCET (June 11, 2020), <https://bit.ly/3l87S13>.

⁷ Francisco Perez-Saez, et al., *Serology-Informed Estimates of SARS-COV-2 Infection Fatality Risk in Geneva, Switzerland*, OSF PREPRINTS (June 15, 2020), <https://osf.io/wdbpe/>.

Another corollary is that the community benefit from vaccines mandates is orders of magnitude lower for a university compared to say a nursing home, where the average age is much higher.

Both Vaccine Immunity and Natural Immunity Provide Durable Protection Against Reinfection and Against Severe Outcomes If Reinfected

15. Both vaccine-mediated immunity and natural immunity after recovery from COVID infection provide extensive protection against severe disease from subsequent SARS-CoV-2 infection. There has never been a reason to presume that vaccine immunity provides a higher level of protection than natural immunity, and there is now evidence that natural immunity is stronger than vaccine immunity. Since vaccines arrived one year after the disease, there is also stronger evidence for long lasting immunity from natural infection than from the vaccines.

16. Both types are based on the same basic immunological mechanism—stimulating the immune system to generate an antibody response. In clinical trials, the efficacy of those vaccines was initially tested by comparing the antibodies level in the blood of vaccinated individuals to those who had natural immunity. Later Phase III studies of the vaccines established 94%+ clinical efficacy of the mRNA vaccines against severe COVID illness.^{8,9} A Phase III trial showed 85% efficacy for the Johnson and Johnson adenovirus-based vaccine against severe disease.¹⁰

⁸ Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, Diemert D, Spector SA, Rouphael N, Creech CB, McGettigan J, Khetan S, Segall N, Solis J, Brosz A, Fierro C, Schwartz H, Neuzil K, Corey L, Gilbert P, Janes H, Follmann D, Marovich M, Mascola J, Polakowski L, Ledgerwood J, Graham BS, Bennett H, Pajon R, Knightly C, Leav B, Deng W, Zhou H, Han S, Ivarsson M, Miller J, Zaks T., *COVE Study Group. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine*, N ENGL J MED (Feb. 4, 2021).

⁹ Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, Perez JL, Pérez Marc G, Moreira ED, Zerbini C, Bailey R, Swanson KA, Roychoudhury S, Koury K, Li P, Kalina WV, Cooper D, Frenck RW Jr, Hammitt LL, Türeci Ö, Nell H, Schaefer A, Ünal S, Tresnan DB, Mather S, Dormitzer PR, Şahin U, Jansen KU, Gruber WC, *Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine*, N ENGL J MED. (Dec. 31, 2020).

¹⁰ Sadoff J, Gray G, Vandebosch A, Cárdenas V, Shukarev G, Grinsztejn B, Goepfert PA, Truyers C, Fennema H, Spiessens B, Offergeld K, Scheper G, Taylor KL, Robb ML, Treanor J, Barouch DH, Stoddard J, Ryser MF, Marovich MA, Neuzil KM, Corey L, Cauwenberghs N, Tanner T, Hardt K, Ruiz-Guiñazú J, Le Gars M, Schuitemaker H, Van Hoof J, Struyf F, Douoguih M, *Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19*, N ENGL J MED (June 10, 2021), 2187-2201.

17. Immunologists have identified many immunological mechanisms of immune protection after recovery from infections. Studies have demonstrated prolonged immunity with respect to memory T and B cells¹¹, bone marrow plasma cells¹², spike-specific neutralizing antibodies¹³, and IgG+ memory B cells¹⁴ following naturally acquired immunity.

18. Multiple extensive, peer-reviewed studies comparing natural and vaccine immunity have now been published. These studies show that natural immunity provides greater protection against severe infection than immunity generated by mRNA vaccines (Pfizer and Moderna).

19. Specifically, studies confirm the efficacy of natural immunity against reinfection of COVID-19¹⁵ and show that the vast majority of reinfections are less severe than first-time

¹¹ Jennifer M. Dan, et al., *Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection*, SCIENCE (Feb. 5, 2021) (finding that memory T and B cells were present up to eight months after infection, noting that “durable immunity against secondary COVID-19 disease is a possibility for most individuals”).

¹² Jackson S. Turner, et al., *SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans*, NATURE (May 24, 2021) (study analyzing bone marrow plasma cells of recovered COVID-19 patients reported durable evidence of antibodies for at least 11 months after infection, describing “robust antigen-specific, long-lived humoral immune response in humans”); Ewen Callaway, *Had COVID? You’ll probably make antibodies for a lifetime*, NATURE (May 26, 2021), <https://www.nature.com/articles/d41586-021-01442-9#:~:text=Many%20people%20who%20have%20been,recovered%20from%20COVID%2D191> (“The study provides evidence that immunity triggered by SARS-CoV-2 infection will be extraordinarily long-lasting” and “people who recover from mild COVID-19 have bone-marrow cells that can churn out antibodies for decades”).

¹³ Tyler J. Ripberger, et al., *Orthogonal SARS-Cov-2 Serological Assays Enable Surveillance of Low-Prevalence Communities and Reveal Durable Humor Immunity*, 53 IMMUNITY, Issue 5, pp. 925-933 E4 (Nov. 17, 2020) (study finding that spike and neutralizing antibodies remained detectable 5-7 months after recovering from infection).

¹⁴ Kristen W. Cohen, et al., *Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells*, MEDRXIV (Apr. 27, 2021), <https://www.medrxiv.org/content/10.1101/2021.04.19.21255739v1> (study of 254 recovered COVID patients over 8 months “found a predominant broad-based immune memory response” and “sustained IgG+ memory B cell response, which bodes well for rapid antibody response upon virus re-exposure.” “Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients”).

¹⁵ Nabin K. Shrestha, et al., *Necessity of COVID-19 vaccination in previously infected individuals*, MEDRXIV (preprint),

<https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3>. (“not one of the 1359 previously infected subjects who remained unvaccinated had a SARS-CoV-2 infection over the duration of the study “and concluded that those with natural immunity are “unlikely to benefit from covid-19 vaccination”); Galit Perez, et al., *A 1 to 1000 SARS-CoV-2 reinfection proportion in members of a large healthcare provider in Israel: a preliminary report*, MEDRXIV (Mar. 8, 2021), <https://www.medrxiv.org/content/10.1101/2021.03.06.21253051v1> (Israeli study finding that approximately 1/1000 of participants were reinfected); Roberto Bertollini, et al., *Associations of Vaccination and of Prior Infection With Positive PCR Test Results for SARS-CoV-2 in Airline Passengers Arriving in Qatar*, JAMA (June 9, 2021), <https://jamanetwork.com/journals/jama/fullarticle/2781112?resultClick=1> (study of international airline passengers arriving in Qatar found no statistically significant difference in risk of reinfection between those who had been vaccinated and those who had previously been infected); Stefan Pilz, et al., *SARS-CoV-2 re-infection risk in Austria*, EUR. J. CLIN. INVEST. (2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7988582/> (previous

infections.¹⁶ For example, an Israeli study of approximately 6.4 million individuals demonstrated that natural immunity provided excellent protection in preventing COVID-19 infection, morbidity, and mortality.¹⁷ Of the 187,549 unvaccinated persons with natural immunity in the study, only 894 (0.48%) were reinfected; 38 (0.02%) were hospitalized, 16 (0.008%) were hospitalized with severe disease, and only one died, an individual over 80 years of age.

20. A more recent study from Israel directly compare natural immunity with vaccine immunity.¹⁸ The study compares previously infected and recovered individuals who did not receive a vaccine after their recovery against individuals who received the Pfizer vaccine without having had the disease. The study considered four primary endpoints: a positive COVID test (a surrogate endpoint of limited value); symptomatic COVID-19 disease, hospitalization for COVID-

SARS-CoV-2 infection reduced the odds of re-infection by 91% compared to first infection in the remaining general population); Aodhan Sean Breathnach, et al., *Prior COVID-19 protects against reinfection, even in the absence of detectable antibodies*, 82 J. OF INFECTION e11-e12 (2021) <https://doi.org/10.1016/j.jinf.2021.05.024> (.0.86% of previously infected population in London became reinfected); Alison Tarke, *Negligible impact of SARS0CoV-2 variants on CD4 and CD8 T cell reactivity in COVID-19 exposed donors and vaccines*, BIORXIV (Mar. 1, 2021), <https://www.biorxiv.org/content/10.1101/2021.02.27.433180v1> (an examination of the comparative efficacy of T cell responses to existing variants from patients with natural immunity compared to those who received an mRNA vaccine found that the T cell responses of both recovered Covid patients and vaccines were effective at neutralizing mutations found in SARS-CoV-2 variants).

¹⁶ Laith J. Abu-Raddad, et al., *SARS-CoV-2 reinfection in a cohort of 43,000 antibody-positive individuals followed for up to 35 weeks*, MEDRXIV (Feb. 8, 2021), <https://www.medrxiv.org/content/10.1101/2021.01.15.21249731v2> (finding that of 129 reinfections from a cohort of 43,044, only one reinfection was severe, two were moderate, and none were critical or fatal); Victoria Jane Hall, et al., *SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study*, 397 LANCET: 1459-69 (Apr. 9, 2021), <https://pubmed.ncbi.nlm.nih.gov/33844963/> (finding “a 93% lower risk of COVID-19 symptomatic infection... [which] show[s] equal or higher protection from natural infection, both for symptomatic and asymptomatic infection”); Aidan T. Hanrahan, et al., *Prior SARS-CoV-2 infection is associated with protection against symptomatic reinfection*, 82 JOURNAL OF INFECTION, Issue 4, E29-E30 (Apr. 1, 2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7832116/> (Apr. 1, 2021) (examined reinfection rates in a cohort of healthcare workers and found “no symptomatic reinfections” among those examined and that protection lasted for at least 6 months).

¹⁷ Yair Goldberg, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2. vaccine protection: A three-month nationwide experience from Israel*, MEDRXIV (pre-print), <https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1>.

¹⁸ Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon (2021) Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections. *medRxiv*. August 25, 2021. doi: <https://doi.org/10.1101/2021.08.24.21262415>.

19 disease, and COVID-19 associated mortality (all recorded in the months after recovery or vaccination). The study adjusts for age, demographic variables, patient comorbidities, and the timing of the disease/vaccine. The primary findings are that vaccinated individuals had 13.1 times higher risk of testing positive [95% CI: 8.08-21.1], 27 times higher risk of symptomatic disease [95% CI: 12.7-57.5], ~8.1 times higher risk of COVID-related hospitalization [95% CI: 1.01-64.55]. None of the patients in the study died due to COVID-related mortality. The vaccinated individuals were also at higher risk compared to those that had COVID diseases before the vaccines became available. The authors concluded:

This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity.

21. Based on such evidence, many scientists have concluded that natural protection against severe disease after COVID recovery is likely to be long-lasting.¹⁹

22. These findings of highly durable natural immunity should not be surprising, as they hold for SARS-CoV-1 and other respiratory viruses. According to a paper published in *Nature* in August 2020, 23 patients who had recovered from SARS-CoV-1 still possess CD4 and CD8 T cells, 17 years after infection during the 2003 epidemic.²⁰ A *Nature* paper from 2008 found that 32 people born in 1915 or earlier still retained some level of immunity against the 1918 flu strain—some 90 years later.²¹

¹⁹ Chris Baranjkuk, *How long does covid-19 immunity last?* 373 BMJ (2021) (emphasis added).

²⁰ Nina Le Bert, *SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control*, NATURE (Aug. 2020).

²¹ Xiacong Yu, et al., *Neutralizing antibodies derived from the B cells of 1918 influenza pandemic survivors*, NATURE (2008).

23. In contrast to the concrete findings regarding the robust durability of natural immunity, it is yet unclear in the scientific literature how long-lasting vaccine-induced immunity will be. Notably, researchers have argued that they can best surmise the predicted durability of vaccine immunity by looking at the expected durability of natural immunity.²²

24. In short, there is no medical or scientific reason to believe that vaccine immunity is superior to or will prove longer-lasting than natural immunity, much less that all currently approved vaccines will be expected to prove more durable than natural immunity despite their different technological foundations and dosing protocols.

Vaccine Side Effects Do Occur, Including Rare But Deadly Side Effects

25. Though the COVID vaccines are safe by the standards of many other vaccines approved for use in the population, like all medical interventions, they have side effects. In summarizing the evidence on vaccine side effects, the CDC lists both common side effects, at least one of which occurs in over half of all people who receive the vaccines, as well as deadly side effects that occur rarely in demographic subsets of the vaccinated population.

26. The common side effects include pain and swelling at the vaccination site and fatigue, headache, muscle pain, fever, and nausea for a limited time after vaccination.²³ Less common but severe side effects also include severe and non-severe allergic (anaphylactic) reactions that can occur within 30 minutes after vaccination, which can typically be treated with an epinephrine injection if it occurs.²⁴ Finally, the CDC's vaccine safety committee has identified

²² Heidi Ledford, *Six months of COVID vaccines: what 1.7 billion doses have taught scientists*, 594 NATURE 164 (June 10, 2021), <https://www.nature.com/articles/d41586-021-01505-x> (study notes that "Six months is not much time to collect data on how durable vaccine responses will be.... In the meantime some researchers are looking to natural immunity as a guide.").

²³ Centers for Disease Control, *Possible Side Effects After Getting a COVID-19 Vaccine* (June 24, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html>.

²⁴ Centers for Disease Control, *What to Do If You Have an Allergic Reaction after Getting a COVID-19 Vaccine* (June 24, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html>.

rare but deadly side effects, including a heightened risk of clotting abnormalities²⁵ in young women after the Johnson & Johnson (J&J) vaccination, elevated risks of myocarditis and pericarditis²⁶ in young people — but especially young men — after mRNA vaccination, and higher risk of Guillane-Barre Syndrome²⁷ after the J&J vaccine. There is still the possibility of severe side effects that have yet to be identified as the vaccines have been in use in human populations for less than a year. Active investigation to check for safety problems is still ongoing.

27. Though the CDC²⁸ still recommends the vaccines for children 12 years old and up despite the evidence of elevated risk of myocarditis, other analysts²⁹ have objected to overly rosy assumptions made in the CDC analysis about vaccine side effects. They suggest that the recommendation is fragile to minor perturbation in their assumptions. The critical point for our analysis – undisputed in the scientific literature – is that the vaccines do have side effects, some of which are severe and not all of which are necessarily known at this point in time.

28. While uncertain, some clinical evidence indicates that those who have recovered from COVID-19 could potentially have a *heightened* risk of adverse effects compared with those

²⁵ Martin Kulldorff, *The Dangers of Pausing the J&J Vaccine*, THE HILL (April 17, 2021), <https://thehill.com/opinion/healthcare/548817-the-dangers-of-pausing-the-jj-vaccine>.

²⁶ Centers for Disease Control, *Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults* (May 28, 2021), <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>.

²⁷ LaFranier and Weiland, *FDA Attaches Warning of Rare Nerve Syndrome to Johnson & Johnson Vaccine*, NEW YORK TIMES (July 12, 2021), <https://www.nytimes.com/2021/07/12/us/politics/fda-warning-johnson-johnson-vaccine-nerve-syndrome.html>.

²⁸ Walensky, *CDC Director Statement on Pfizer's Use of COVID-19 Vaccine in Adolescents Age 12 and Older* (May 12, 2021), <https://www.cdc.gov/media/releases/2021/s0512-advisory-committee-signing.html>.

²⁹ Pegden, *Weighing myocarditis cases, ACIP failed to balance the harms vs benefits of 2nd doses* (June 24, 2021), <https://medium.com/@wpegden?p=d7d6b3df7cfb>.

who have never had the virus.^{30 31} This may be because vaccine reactogenicity after the first dose is higher among those with prior natural immunity.³²

Variants Do Not Alter the Conclusion that Vaccine Mandates Are Unwarranted

29. Since its spread through the human population, the SARS-CoV-2 virus – an RNA virus – has been mutating, including some forms that are likely more transmissible than the original wild-type virus that emerged from Wuhan, China, in 2019. The virus will continue to mutate as it continues to spread. However, the possibility of such a mutation does not alter the conclusion that a vaccine mandate is unwarranted.

30. First, the mutant variants do not escape the immunity provided by prior infection with the wild-type virus or vaccination.^{33,34,35} Although reinfection can occur, people who have been previously infected by the wild-type (non-variant) virus are unlikely to have a severe outcome

³⁰ Alexander G. Mathioudakis, et al., *Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey*, 11 LIFE 249 (Mar. 2021).

³¹ Cristina Menni, *Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID symptom study app in the UK: a prospective observational study*, 21 LANCET INFECTIOUS DISEASES 939-49 (July 2021) (finding that “Systemic side-effects were more common (1.6 times after the first dose of ChAdOx1 nCoV-19 [i.e., AstraZeneca vaccine] and 2.9 times after the first dose of BNT162b2 [i.e., Pfizer/BioNTech vaccine]) among individuals with previous SARS-CoV-2 infection than among those without known past infection. Local effects were similarly higher in individuals previously infected than in those without known past infection (1.4 times after the first dose of ChAdOx1 nCoV-19 and 1.2 times after the first dose of BNT162b2).”).

³² Florian Krammer, et al., *Robust spike antibody responses and increased reactogenitiy in seropositive individuals after a sinige dose of SARS-CoV-2 mRNA vaccine*, MEDRXIV (Feb. 1, 2021), <https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1> (concluding that “vaccine reactogenicity after the first dose is substantially more pronounced in individuals with pre-existing immunity.” The authors note that “quantitative serological assays that measure antibodies to the spike protein could be used to screen individuals prior to vaccination,” which would “limit the reactogenicity experienced by COVID-19 survivors.”).

³³ Alison Tarke, A., Sidney, J., Methot, N., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., da Silva Antunes, R., Frazier, A., Rawlings, S. A., Smith, D. M., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A., & Sette, A., *Negligible impact of SARS-CoV-2 variants on CD4 + and CD8 + T cell reactivity in COVID-19 exposed donors and vaccinees*, BIORXIV, 2021.02.27.433180 (2021), <https://doi.org/10.1101/2021.02.27.433180>.

³⁴ Wu, K., Werner, A. P., Moliva, J. I., Koch, M., Choi, A., Stewart-Jones, G. B. E., Bennett, H., Boyoglu-Barnum, S., Shi, W., Graham, B. S., Carfi, A., Corbett, K. S., Seder, R. A., & Edwards, D. K., *mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants*, BIORXIV : THE PREPRINT SERVER FOR BIOLOGY, 2021.01.25.427948 (2021), <https://doi.org/10.1101/2021.01.25.427948>.

³⁵ Redd, A. D., Nardin, A., Kared, H., Bloch, E. M., Pekosz, A., Laeyendecker, O., Abel, B., Fehlings, M., Quinn, T. C., & Tobian, A. A., *CD8+ T cell responses in COVID-19 convalescent individuals target conserved epitopes from multiple prominent SARS-CoV-2 circulating variants*, MEDRXIV : THE PREPRINT SERVER FOR HEALTH SCIENCES, 2021.02.11.21251585 (2021), <https://doi.org/10.1101/2021.02.11.21251585>.

(hospitalization or death) after exposure to a variant virus. A variant circulating in the population thus poses little additional risk of hospital overcrowding or excess mortality due to viral infection.

31. Second, theoretical work suggests that lockdowns place selective pressure that promotes the development and establishment of more deadly variants. This, in part, may explain why the most concerning variants have emerged in places like the U.K., South Africa, and California, where severe lockdowns have been imposed for extended periods.³⁶ While this hypothesis awaits a definitive empirical test, it is consistent with the *prima facie* evidence on mutant variants' development.

32. Third, the variants have been widely spreading in many countries these past months, even as cases have dropped. This is true, for instance, in Florida, where the U.K. variant B.1.1.7 was widespread this past winter³⁷, but cases fell sharply over the same period that the variant has been spreading. That variants with an infectivity advantage – but no more lethality – make up a larger fraction of a smaller number of cases is an interesting scientific observation but not crucial for public health policy.

33. Fourth, the dissemination of vaccines that protect against hospitalizations and deaths upon COVID-19 infection throughout the older population in the United States has decoupled the growth in COVID-19 cases from COVID-19 mortality. Vaccinated people can still perhaps be infected but rarely have severe symptoms in response to infection. Throughout last year, a rise in cases was inevitably accompanied by an increase in deaths with a two-to-three-week lag. However, during this most recent wave, there has been little rise in daily deaths to accompany the rise in cases because of the deployment of the vaccine in the vulnerable older population in the

³⁶ Moran J., *Mutant variations and the danger of lockdowns*, THE CRITIC MAGAZINE (March 2, 2021), <https://thecritic.co.uk/mutant-variations-and-the-danger-of-lockdowns/>.

³⁷ US Centers for Disease Control, *US COVID-19 Cases Caused by Variants* (2021), <https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html>.

United States. The same is true in Sweden and the U.K., where vaccines have been provided to the entirety of the vulnerable elderly population and more.³⁸ Because of the success of the American vaccination effort among the vulnerable elderly, COVID-19 cases and COVID-19 deaths are now effectively decoupled.

The Presence of Lingering Post-Viral Infection Symptoms in a Subset of Recovered COVID patients (“Long COVID”) Does Not Alter The Conclusion that Vaccine Mandates Are Unwarranted

34. Some analysts and politicians have used the possibility that a fraction of patients who recover from COVID infection will experience lingering symptoms to justify vaccine mandates and lockdown measures. Long COVID, as this phenomenon is called, includes a complex set of clinical outcomes with a poorly understood link to acute COVID infection.³⁹ One cross-sectional study found that about 30% of recovered COVID patients reported at least one symptom months after recovery, with fatigue and anosmia (loss of sense of smell) by far the most common.⁴⁰ A separate study with a more convincing longitudinal methodology, by contrast, concluded that 2.3% of patients experienced such symptoms three months after recovery.⁴¹ Patients who suffered a more severe acute course of COVID, including hospitalization, were more likely to report lingering symptoms after recovery.⁴² A study of children who recovered from

³⁸Jay Bhattacharya, Martin Kulldorff, and Sunetra Gupta, *Sweden’s Lessons for the UK’s Third Wave*, THE SPECTATOR (July 12, 2021), <https://www.spectator.co.uk/article/sweden-shows-that-the-uk-s-third-wave-won-t-sting>.

³⁹Nalbandian, A., Sehgal, K., Gupta, A. et al., *Post-acute COVID-19 syndrome*, NAT MED 27, 601–615 (2021), <https://doi.org/10.1038/s41591-021-01283-z>.

⁴⁰Logue JK, Franko NM, McCulloch DJ, et al., *Sequelae in Adults at 6 Months After COVID-19 Infection*, JAMA NETW OPEN (2021);4(2):e210830, doi:10.1001/jamanetworkopen.2021.0830.

⁴¹Sudre, C.H., Murray, B., Varsavsky, T. et al., *Attributes and predictors of long COVID*, NAT MED 27, 626–631 (2021), <https://doi.org/10.1038/s41591-021-01292-y>.

⁴²Arnold DT, Hamilton FW, Milne A, et al., *Patient outcomes after hospitalisation with COVID-19 and implications for follow-up: results from a prospective UK cohort*, THORAX, 76:399-401 (2021).

COVID found the same rate of long COVID symptoms as a control group of children who had no serological evidence of prior COVID infection.⁴³ Some analysts have noted the similarity between “long COVID” symptoms and other functional somatic syndromes that sometimes occur after other viral infections and other triggers (and sometimes with no identifiable etiology).⁴⁴

35. To summarize, as with other viruses, long COVID symptoms occur in a minority of patients who recover from COVID and pose a real burden on patients who suffer from it. However, this fact does not alter the logic of our argument. On the contrary. After suffering through COVID, with or without long COVID, such individuals should not be forced to also endure common but mild vaccine adverse reactions or risk rare but serious adverse reactions. Moreover, the successful vaccine rollout in the United States – where every teenager and adult has free access to the vaccines – addresses the problem of long COVID, just as it addresses COVID-associated mortality.

CDC Recommendation for Vaccination of Recovered COVID Patients Applies With Equal Force to Previously Vaccinated

36. Written before the Israel study, the CDC, in a frequently asked questions section of a website encouraging vaccination, provided the following advice to previously recovered patients in July 2021:⁴⁵

Yes, you should be vaccinated regardless of whether you already had COVID-19. That’s because experts do not yet know how long you are protected from getting sick again after recovering from COVID-19. Even if you have already recovered from COVID-19, it is possible—although rare—that you could be infected with the virus that causes COVID-19 again. Studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19. Learn

⁴³ Thomas Radtke, Agne Ulyte, Milo A Puhan, Susi Kriemler, *Long-term symptoms after SARS-CoV-2 infection in school children: population-based cohort with 6-months follow-up*, MEDRXIV (2021), <https://doi.org/10.1101/2021.05.16.21257255>.

⁴⁴ Ballering A, Olde Hartman T, Rosmalen J Long COVID-19, *persistent somatic symptoms and social stigmatization*, J EPIDEMIOLOG COMMUNITY HEALTH (2021).

⁴⁵ US Centers for Disease Control (2021) Frequently Asked Questions About COVID-19 Vaccination. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html> (accessed July 30, 2021)

more about why getting vaccinated is a safer way to build protection than getting infected.

37. The last sentence is true but irrelevant for people with natural immunity. The statement on CDC's website that "studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19," is incorrect. As one would expect, people with prior COVID-19 disease have increased levels of antibodies after receiving the vaccine, leading to fewer positive tests, just as if they are re-exposed to the disease. This does not mean that the vaccine increases protection against symptomatic disease, hospitalizations or deaths. In an update to the website⁴⁶ on August 19, 2021, the CDC links to a single study from Kentucky.⁴⁷ That study showed fewer positive tests among those who had both natural immunity and a vaccine, but the study did not evaluate the relevant outcomes of symptomatic disease, hospitalizations, deaths or transmission. Like the Kentucky study, the Israel study also found that those with both natural immunity and a vaccine were less likely to test positive compared with those with natural immunity but no vaccine. The Israel study also evaluated other outcomes, and did not find any statistically significant difference with respect to symptomatic disease, hospitalizations or deaths, all of which were very low in both groups (e.g. no deaths in either group).

38. The text of this advice by the CDC also does not address any of the scientific evidence we have provided in our declaration, herein, about the lack of necessity for recovered COVID patients to be vaccinated. While it is true that we do not know how long natural immunity

⁴⁶ US Centers for Disease Control (2021) Frequently Asked Questions About COVID-19 Vaccination. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html> (accessed August 26, 2021)

⁴⁷ Cavanaugh AM, Spicer KB, Thoroughman D, Glick C, Winter K. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:1081–1083. DOI: <http://dx.doi.org/10.15585/mmwr.mm7032e1>

after recovery lasts, in terms of 5, 10, or 20 years from now, the immunological evidence to date suggests that protection against disease will last for years.⁴⁸

39. That is because, with exceedingly few reinfections among millions of recovered COVID-19 patients, we know that there is excellent protection for at least 18 months, and that protection is not suddenly going to disappear after exactly 18 months.

40. Uncertainty over the longevity of immunity after recovery is a specious reason for not exempting COVID recovered patients from vaccination mandates, since the same is true to an even higher degree about vaccine mediated immunity. We do not know how long it will last either, and there is no reason to believe it provides longer lasting or more complete immunity than recovery from COVID.

41. Similarly, just as reinfections are possible though rare after COVID recovery, breakthrough infections are possible after vaccination, as the CDC's team investigating vaccine breakthrough infections itself recognizes.⁴⁹ On the same CDC FAQ webpage we cite above⁵⁰, the CDC writes about vaccine mediated immunity, "We don't know how long protection lasts for those who are vaccinated."

42. The CDC's main concern in this FAQ seems to be to help people understand that it is safer to attain immunity against SARS-CoV-2 infection via vaccination rather than via infection. This is a point not in dispute. Rather, the question is whether someone who already has been infected and recovered will benefit on net from the additional protection provided by vaccination.

⁴⁸ Patel N (2021) Covid-19 Immunity Likely Lasts for Years. MIT Technology Review. January 6, 2021.

<https://www.technologyreview.com/2021/01/06/1015822/covid-19-immunity-likely-lasts-for-years/>

⁴⁹ CDC COVID-19 Vaccine Breakthrough Case Investigations Team (2021) COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021. May 28, 2021.

<https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm>

⁵⁰ US Centers for Disease Control (2021) Frequently Asked Questions About COVID-19 Vaccination.

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>

On this point, the CDC's statement in the FAQ is non-responsive, and ignores the scientific evidence.

Conclusion

43. A fundamental ethical principle guiding the practice of medicine is that any medical intervention, whether surgical, pharmacological, or a vaccine, should be recommended and undertaken only if it is deemed medically necessary. Any medical procedure, including vaccination, involves risk. No medical procedure is 100% safe, especially those involving a new vaccine which by definition has not been studied for long-term adverse side effects. For this reason, it is a fundamental principle of medical ethics that the risks of the procedure be balanced against the potential benefits.

44. As we established earlier, based on the scientific evidence to date, those who have recovered from a SARS-CoV-2 infection possess immunity as robust and durable as that acquired through vaccination. In Jeanna Norris' case, there is no doubt that, based on recent measures of her antibody levels, she is protected by natural immunity (Dr. Bhattacharya has examined the results from Ms. Norris' laboratory tests). The results indicate the presence of both spike-protein and nucleocapsid protein antibodies; the latter is a reliable sign of previous natural infection (the former turns positive after either previous natural infection or vaccination). The existing clinical literature overwhelmingly indicates that the protection afforded to the individual and community from natural immunity is as effective and durable as the efficacy levels of the most effective vaccines to date. From the point of view of Ms. Norris' personal health, there is no good reason that she should be vaccinated. At the very least, the decision should be left to Ms. Norris and her doctors without coercion applied by the University.

45. There is also no community health reason for the University to mandate vaccinations since she already has stonge immunity than those that ae vaccinated, and the vaccine is available to all teens and adults who want it. Indeed, based on our analysis of the existing medical and scientific literature, any policy mandating vaccinations that does not recognize natural immunity is irrational, arbitrary, and counterproductive to community health.⁵¹

46. As we wrote in the *Wall Street Journal* this spring, “[t]he idea that everybody needs to be vaccinated is as scientifically baseless as the idea that nobody does. Covid vaccines are essential for older, high-risk people and their caretakers and advisable for many others. But those who’ve been infected are already immuneIf authorities mandate vaccination of those who don’t need it, the public will start questioning vaccines in general Coercive vaccination policies would erode trust even further.”⁵²

47. We criticized those pushing for and implementing vaccine mandates as “undermining public trust in vaccines. In this sense, they are more dangerous than the small group of so-called anti-vaxxers have ever been.”

48. It is unethical to coerce low-risk Americans to take the vaccine, such as low-risk students and those with natual immunity, while older high-risk individuals in Asia, Africa and Latin America are dying from COVID19 because there are not enough vaccines available in those countries.

49. Now that every American adult and teenager has free access to the vaccines, the case for a vaccine mandate is even weaker than it was in the spring when we wrote that *Wall Street*

⁵¹ Jay Bhattacharya, Sunetra Gupta, and Martin Kulldorff, *The Beauty of Vaccines and Natural Immunity*, SMERCONISH NEWSLETTER (June 4, 2021), <https://www.smerconish.com/exclusive-content/the-beauty-of-vaccines-and-natural-immunity>.

⁵² Martin Kulldorff and Jay Bhattacharya, *Vaccine Passports Prolong Lockdowns*, WALL STREET JOURNAL (Apr. 6, 2021), <https://www.wsj.com/articles/vaccine-passports-prolong-lockdowns-11617726629>.

Journal piece. There is no good public health case for MSU to require proof of vaccination for employees and students to participate in University activities that do not involve care for high-risk patients. And, since those recovered from COVID19 has better protection than vaccinated individuals, there are no public health reasons to impose different mask requirements for the two groups.

50. Since the successful vaccination campaign already protects the vulnerable population, even the unvaccinated who have not had COVID disease –pose a vanishingly small threat to the vaccinated o those with natural immunity. They are protected by an effective vaccine, that dramatically reduces the likelihood of hospitalization or death after infections to near zero, o by natural immunity.

51. With widespread vaccination of the vulnerable, asymptomatic people pose even less risk to the vulnerable than before the vaccine became available. At the same time, the requirement for a vaccine passport or other type of proof of vaccine undermines trust in public health because of its coercive nature. While vaccines are an excellent tool for protecting the vulnerable, COVID does not justify ignoring principles of good public health practice that caution against warrantless discrimination against segments of the population (in this case, the unvaccinated).

52. We recently observed that “[u]niversities used to be bastions of enlightenment. Now many of them ignore basic benefit-risk analyses, a staple of the toolbox of scientists; they deny immunity from natural infection; they abandon the global international perspective for narrow nationalism; and they replace trust with coercion and authoritarianism. Mandating the COVID-19 vaccine thus threatens not only public health but also the future of science.”⁵³

⁵³ Martin Kuldorff and Jay Bhattacharya, *The ill-advised push to vaccinate the young*, THEHILL.COM (June 17, 2021), <https://thehill.com/opinion/healthcare/558757-the-ill-advised-push-to-vaccinate-the-young?rl=1>.

53. Universities can be leaders in developing sensible policies grounded in sound scientific evidence and abide by the fundamental principles of medical ethics. Individuals who have recovered from COVID-19 should be exempt from any vaccine mandates and treated as in an identical position to those who have been vaccinated.

Respectfully submitted,

Dr. Jay Bhattacharya, MD, Ph.D.
Professor of Medicine
Stanford University

Dr. Martin Kulldorff, Ph.D.
Professor of Medicine
Harvard University



EXHIBIT X H

Vaccine Testing and the Approval Process

This page leads to other pages that describe vaccine development and testing such as basic research, clinical studies, side effects and adverse reactions, vaccines of the future, and the vaccine product approval process.

Development of New Vaccines

The general stages of the development cycle of a vaccine are:

- Exploratory stage
- Pre-clinical stage
- Clinical development
- Regulatory review and approval
- Manufacturing
- Quality control

Clinical development is a three-phase process. During Phase I, small groups of people receive the trial vaccine. In Phase II, the clinical study is expanded and vaccine is given to people who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended. In Phase III, the vaccine is given to thousands of people and tested for efficacy and safety.

Many vaccines undergo Phase IV formal, ongoing studies after the vaccine is approved and licensed.

For more information and to find out about new vaccines on the horizon, see the World Health Organization's (WHO's) Development of New Vaccines [web page](#).

Vaccine Product Approval Process

Journey of a New Vaccine: From Development to Licensed for Use

See how a new vaccine is developed, approved, manufactured, added to recommended schedule, and is continually monitored.



The U.S. Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research [\(CBER\)](#) is responsible for regulating vaccines in the United States.

The sponsor of a new vaccine product follows a multi-step approval process, which typically includes

- An Investigational New Drug application
- Pre-licensure vaccine clinical trials

- A Biologics License Application (BLA)
- Inspection of the manufacturing facility
- Presentation of findings to FDA's Vaccines and Related Biological Products Advisory Committee [↗](#) (VRBPAC)
- Usability testing of product labeling

After approving a vaccine, FDA continues to oversee its production to ensure continuing safety. Monitoring of the vaccine and of production activities, including periodic facility inspections, must continue as long as the manufacturer holds a license for the vaccine product.

FDA can require a manufacturer submit the results of their own tests for potency, safety, and purity for each vaccine lot. FDA can require each manufacturer submit samples of each vaccine lot for testing.

To learn about FDA's role in the vaccine approval process, consult FDA's Vaccine Product Approval Process [↗](#) web page.

Tracking Side Effects Once a Vaccine is Administered

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Food and Drug Administration (FDA) and the CDC.

VAERS collects and analyzes information from reports of adverse events (side effects) that occur after the administration of US licensed vaccines. Reports are welcome from all concerned individuals: patients, parents, healthcare providers, pharmacists, and vaccine manufacturers. To submit a report, use VAERS' reporting page [↗](#).

For more information on VAERS, consult VAERS website [↗](#).

[Top of Page](#)

Related Topics and Sources

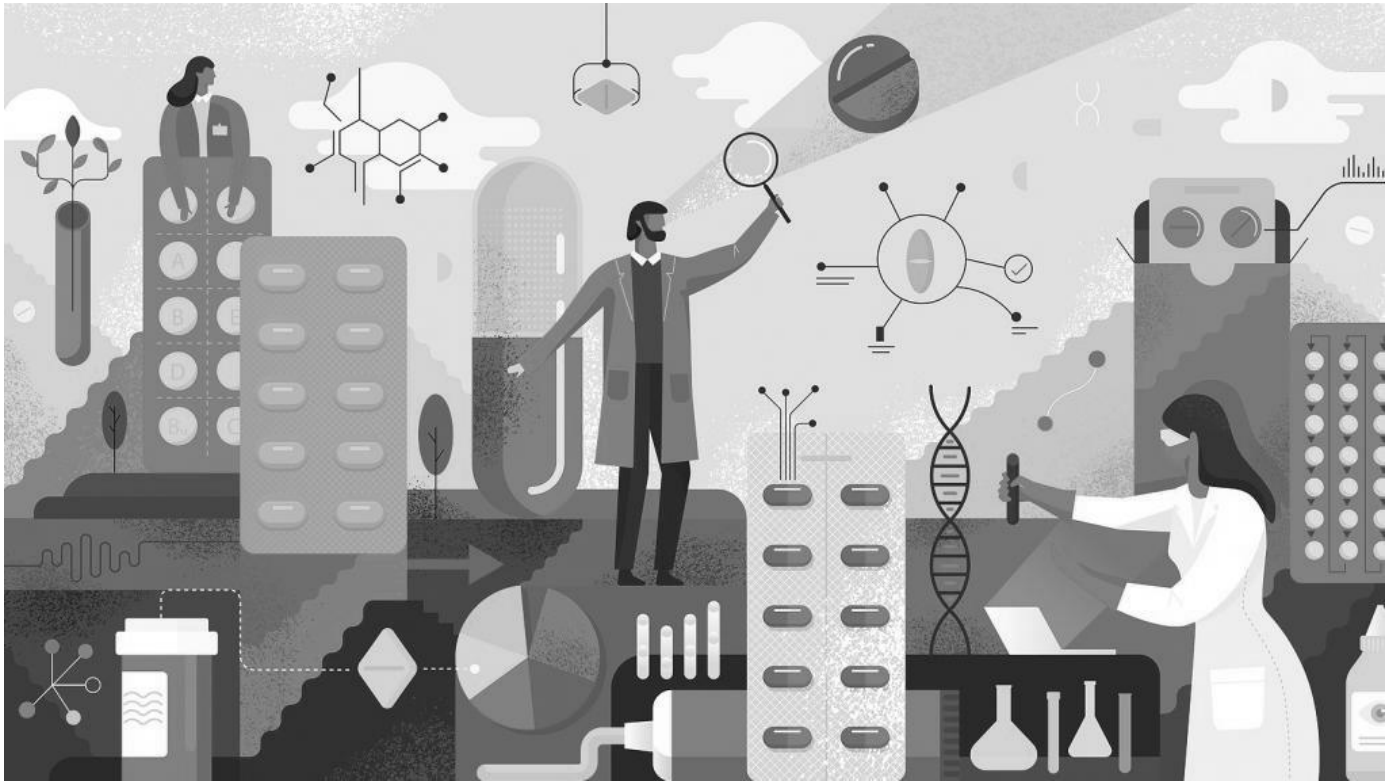
- Vaccine Development, Testing and Regulation [↗](#)
Source: History of Vaccines
- Vaccine Regulation [↗](#)
(World Health Organization)
- FDA's Vaccine Safety & Availability [↗](#)
- Vaccine Adverse Event Reporting System [↗](#) (VAERS)
- CDC's Vaccine Safety

Related Page

National Vaccine Advisory Committee [↗](#) (NVAC)

EXHIBIT X I

Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19



[Download the printer-friendly version of this Consumer Update \(PDF 3.5 MB\) \(/media/138490/download\).](#)

[Español \(/consumers/articulos-en-espanol/entendiendo-la-terminologia-utilizada-para-posibles-medidas-preventivas-y-tratamientos-para-el-covid\)](#)

[简体中文 \(/consumers/consumer-updates/lejieqianzaide2019guanzhuangbingdufeiyanyufanghezhliaooshuyu\)](#)

[한국어 \(/consumers/consumer-updates/kolonabaileoseugameomjeung-covid-19ui-jamjaejeogin-yebang-mich-chilyo-gwanlyeonhan-gyuje-yongeoleul\)](#)

[Tagalog \(/consumers/consumer-updates/pag-unawa-sa-pagkontrol-ng-terminolohiya-ng-potensyal-na-pag-iwas-paggamot-para-sa-covid-19\)](#)

[Việt \(/consumers/consumer-updates/hieu-thuat-ngu-ve-cac-bien-phap-ngan-ngua-va-dieu-tri-tiem-nang-doi-voi-covid-19\)](#)

There's a lot of confusion about which medical products might work to prevent or treat coronavirus disease 2019 (COVID-19). Scientists are working hard to develop a number of potential drugs for the prevention or treatment of coronavirus.

The FDA recently approved the first treatment for COVID-19, the antiviral drug remdesivir. Some other investigational drugs are already in clinical trials. In some cases, scientists are testing whether drugs that are already approved for a different disease are safe and effective against COVID-19.

As studies continue, these drugs are sometimes made available to patients through the FDA's Expanded Access Program, or under an Emergency Use Authorization. Health care providers may also decide to treat a patient with a drug that has been approved by the FDA for one use, but not for the patient's disease or condition (sometimes called "off-label" use).

If you think you have, or have had, COVID-19, your health care provider has a complete picture of your health and health history and can help you make the best decisions for your care.

The language used to describe potential therapies can be confusing, and there's public interest around the FDA's work to ensure access to potentially life-saving treatments. Here's what those terms mean.

What "FDA Approved" Means

U.S. consumers rely on the FDA to provide independent scientific reviews of medical products, including drugs and vaccines. During this public health emergency, there is an urgent need for products to treat or prevent the virus that causes COVID-19.

Before the FDA can approve a drug, the agency must determine whether the clinical data and other information show that the drug is safe and effective for its intended use (for example, to prevent or treat a certain disease), and that the product can be made according to federal quality standards.

When the FDA approves a drug, it means the agency has determined, based on substantial evidence, that the drug is effective for its intended use, and that the benefits of the drug outweigh its risks when used according to the product's approved labeling.

The FDA is working with manufacturers and researchers to make sure the agency is getting the information needed to complete that evaluation for drugs to treat or prevent COVID-19 as quickly as possible.

Investigational Treatments

An [investigational drug](/patients/learn-about-expanded-access-and-other-treatment-options/understanding-investigational-drugs) (</patients/learn-about-expanded-access-and-other-treatment-options/understanding-investigational-drugs>) can also be called an experimental drug. Scientists conduct clinical trials to study investigational drugs to see if they can safely and effectively prevent or treat a specific disease or condition. As part of those clinical trials, they might try to discover:

- How the drug might be used for that disease or condition.
- If the drug is safe for people.
- How much of the drug is needed.
- Information about whether it works against the disease and the potential benefits and risks of taking the drug.

Expanded Access

Sometimes called "compassionate use," [expanded access](/news-events/expanded-access/expanded-access-information-patients) (</news-events/expanded-access/expanded-access-information-patients>) is a potential pathway for a patient with a serious or [immediately life-threatening disease or condition](/news-events/expanded-access/expanded-access-keywords-definitions-and-resources) (</news-events/expanded-access/expanded-access-keywords-definitions-and-resources>) to gain access to an [investigational medical product](/news-events/expanded-access/expanded-access-keywords-definitions-and-resources) (</news-events/expanded-access/expanded-access-keywords-definitions-and-resources>)(drug, biological product, or medical device) for treatment outside of clinical trials when there is no comparable or satisfactory alternative therapy.

Currently, expanded access is one pathway for use of [COVID-19 convalescent plasma](/vaccines-blood-biologics/investigational-new-drug-applications-inds-cber-regulated-products/recommendations-investigational-covid-19-convalescent-plasma) (</vaccines-blood-biologics/investigational-new-drug-applications-inds-cber-regulated-products/recommendations-investigational-covid-19-convalescent-plasma>) for patients with serious or immediately life-threatening COVID-19 disease who are not eligible for or who are unable to participate in randomized clinical trials.

Limited information suggests that [convalescent plasma \(/about-fda/page-not-found\)](#) – an antibody-rich product made from blood donated by people who have recovered from the virus – may help COVID-19 patients. Because current information is limited, it’s important to evaluate this therapy in the context of a clinical trial.

Emergency Use Authorization (EUA)

An Emergency Use Authorization (EUA) is one of several tools the FDA is using to help make certain medical products available quickly during the COVID-19 pandemic. In certain emergencies, the FDA can issue an EUA to provide access to medical products that may potentially be used when there are no adequate, approved, and available options.

The EUA process is different than an FDA approval or clearance. Under an EUA, in an emergency, the FDA makes a product available to the public based on the best available evidence, without waiting for all the evidence that would be needed for FDA approval or clearance.

When evaluating an EUA, we carefully balance the potential risks and benefits of the products based on the data currently available.

EUAs are effective until the emergency declaration ends. EUAs can also be revised or revoked by the FDA at any time as we continue to evaluate the available data and patient needs during the public health emergency.

The FDA has granted EUAs to a few possible COVID-19 therapies. Learn more about EUAs [in this video \(https://www.youtube.com/watch?v=iGkwaESsGBQ&feature=youtu.be\)](#) [↗](#) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>).

“Off-Label” Use: Unapproved Uses of Approved Drugs

Once the FDA has approved a drug for a disease or medical condition, health care providers generally may prescribe or administer the drug in clinical practice for an unapproved use not described in the approved labeling (i.e., “off-label”) based on their medical judgment, recognizing that the FDA has not assessed the safety or effectiveness of such use.

Emergency Use Authorization for Vaccines Explained

Español (<https://www.fda.gov/vaccines-blood-biologics/vaccines/explicacion-de-la-autorizacion-de-uso-de-emergencia-para-las-vacunas>)

FDA is globally respected for its scientific standards of vaccine safety, effectiveness and quality. The agency provides scientific and regulatory advice to vaccine developers and undertakes a rigorous evaluation of the scientific information through all phases of clinical trials, which continues after a vaccine has been approved by FDA or authorized for emergency use.

FDA recognizes the gravity of the current public health emergency and the importance of facilitating availability, as soon as possible, of vaccines to prevent COVID-19 - vaccines that the public will trust and have confidence in receiving.

What is an Emergency Use Authorization (EUA)?

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives. Taking into consideration input from the FDA, manufacturers decide whether and when to submit an EUA request to FDA.

Once submitted, FDA will evaluate an EUA request and determine whether the relevant statutory criteria are met, taking into account the totality of the scientific evidence about the vaccine that is available to FDA.

Are the COVID-19 vaccines rigorously tested?

Yes. Clinical trials are evaluating investigational COVID-19 vaccines in tens of thousands of study participants to generate the scientific data and other information needed by FDA to determine safety and effectiveness. These clinical trials are being conducted according to the rigorous standards set forth by the FDA.

Initially, in phase 1, the vaccine is given to a small number of generally healthy people to assess its safety at increasing doses and to gain early information about how well the vaccine works to induce an immune response in people. In the absence of safety concerns from phase 1 studies, phase 2 studies include more people, where various dosages are tested on hundreds of people with typically varying health statuses and from different demographic groups, in randomized-controlled studies. These studies provide additional safety information on common short-term side effects and risks, examine the relationship between the dose administered and the immune response, and may provide initial information regarding the effectiveness of the vaccine. In phase 3, the vaccine is generally administered to thousands of people in randomized, controlled studies involving broad demographic groups (i.e., the population intended for use of the vaccine) and generates critical information on effectiveness and additional important safety data. This phase provides additional information about the immune response in people who receive the vaccine compared to those who receive a control, such as a placebo.

What safety and effectiveness data are required to be submitted to FDA for an EUA request for a vaccine intended to prevent COVID-19?

COVID-19 vaccines are undergoing a rigorous development process that includes tens of thousands of study participants to generate the needed non-clinical, clinical, and manufacturing data. FDA will undertake a comprehensive evaluation of this information submitted by a vaccine manufacturer.

For an EUA to be issued for a vaccine, for which there is adequate manufacturing information to ensure quality and consistency, FDA must determine that the known and potential benefits outweigh the known and potential risks of the vaccine. An EUA request for a COVID-19 vaccine can be submitted to FDA based on a final analysis of a phase 3 clinical efficacy trial or an interim analysis of such trial, i.e., an analysis performed before the planned end of the trial once the data have met the pre-specified success criteria for the study's primary efficacy endpoint.

From a safety perspective, FDA expects an EUA submission will include all safety data accumulated from phase 1 and 2 studies conducted with the vaccine, with an expectation that phase 3 data will include a median follow-up of at least 2-months (meaning that at least half of vaccine recipients in phase 3 clinical trials have at least 2 months of follow-up) after completion of the full vaccination regimen. In

addition, FDA expects that an EUA request will include a phase 3 safety database of well over 3,000 vaccine recipients, representing a high proportion of participants enrolled in the phase 3 study, who have been followed for serious adverse events and adverse events of special interest for at least one month after completion of the full vaccination regimen.

Part of FDA's evaluation of an EUA request for a COVID-19 vaccine includes evaluation of the chemistry, manufacturing, and controls information for the vaccine. Sufficient data should be submitted to ensure the quality and consistency of the vaccine product. FDA will use all available tools and information, including records reviews, site visits, and previous compliance history, to assess compliance with current good manufacturing practices.

What is the process that manufacturers are following to potentially make a COVID-19 vaccine available by EUA?

- Vaccine manufacturers are undertaking a development process that includes tens of thousands of study participants to generate non-clinical, clinical, and manufacturing information needed by FDA for the agency to determine whether the known and potential benefits outweigh the known and potential risks of a vaccine for the prevention of COVID-19.
- When the phase 3 portion of the human clinical trial reaches a predetermined point that informs how well a vaccine prevents COVID-19, as discussed and agreed to in advance with FDA, an independent group (called a data safety monitoring board) will review the data and inform the manufacturer of the results. Based on the data and the interpretation of the data by this group, manufacturers decide whether and when to submit an EUA request to FDA, taking into consideration input from FDA.
- After FDA receives an EUA request, our career scientists and physicians will evaluate all of the information included in the manufacturer's submission.
- While FDA's evaluation is ongoing, we will also schedule a public meeting of our Vaccines and Related Biological Products Advisory Committee, which is made up of external scientific and public health experts from throughout the country. During the meeting, these experts, who are carefully screened for any potential conflicts of interest, will discuss the safety and effectiveness data so that the public and scientific community will have a clear understanding of the data and information that FDA is evaluating to make a decision whether to authorize a COVID-19 vaccine for emergency use.
- Following the advisory committee meeting, FDA's career professional staff will consider the input of the advisory committee members and continue their evaluation of the submission to determine whether the available safety and effectiveness and manufacturing data support an emergency use authorization of the specific COVID-19 vaccine in the United States.

Who are the FDA career professionals evaluating EUAs for vaccines?

The FDA staff are career scientists and physicians who have globally recognized expertise in the complexity of vaccine development and in evaluating the safety and effectiveness of all vaccines intended to prevent infectious diseases. These FDA professionals are committed to decision-making based on scientifically driven evaluation of data. FDA staff are like your family - they are fathers, mothers, daughters, sons, sisters, brothers and more. They and their families are also directly impacted by the work that they do, and are exactly who you want making these important public health decisions for the United States.

What are the plans for continued monitoring of COVID-19 vaccines authorized by FDA for emergency use?

FDA expects vaccine manufacturers to include in their EUA requests a plan for active follow-up for safety, including deaths, hospitalizations, and other serious or clinically significant adverse events, among individuals who receive the vaccine under an EUA, to inform ongoing benefit-risk determinations to support continuation of the EUA.

FDA also expects manufacturers who receive an EUA to continue their clinical trials to obtain additional safety and effectiveness information and pursue licensure (approval).

Post-authorization vaccine safety monitoring is a federal government responsibility shared primarily by FDA and the U.S. Centers for Disease Control and Prevention (CDC), along with other agencies involved in healthcare delivery. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. There will be multiple, complementary systems in place with validated analytic methods that can rapidly detect signals for possible vaccine safety problems. The U.S. government has a well-established post-authorization/post-approval vaccine safety monitoring infrastructure that will be scaled up to meet the needs of a large-scale COVID-19 vaccination program. The U.S. government – in partnership with health systems, academic centers, and private sector partners – will use multiple existing vaccine safety

monitoring systems to monitor COVID-19 vaccines in the post-authorization/approval period. Some of these systems are the Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink (VSD), the Biologics Effectiveness and Safety (BEST) Initiative, and Medicare claims data.

How will vaccine recipients be informed about the benefits and risks of any vaccine that receives an EUA?

FDA must ensure that recipients of the vaccine under an EUA are informed, to the extent practicable given the applicable circumstances, that FDA has authorized the emergency use of the vaccine, of the known and potential benefits and risks, the extent to which such benefits and risks are unknown, that they have the option to accept or refuse the vaccine, and of any available alternatives to the product. Typically, this information is communicated in a patient “fact sheet.” The FDA posts these fact sheets on our website.

How is it that COVID-19 vaccines have been developed so quickly?

In public health emergencies, such as a pandemic, the development process may be atypical. For example, as demonstrated by the response to the COVID-19 pandemic, the U.S. government has coalesced government agencies, international counterparts, academia, nonprofit organizations and pharmaceutical companies to develop a coordinated strategy for prioritizing and speeding development of the most promising vaccines. In addition, the federal government has made investments in the necessary manufacturing capacity at its own risk, giving companies confidence that they can invest aggressively in development and allowing faster distribution of an eventual vaccine. However, efforts to speed vaccine development to address the ongoing COVID-19 pandemic have not sacrificed scientific standards, integrity of the vaccine review process, or safety.

Recognizing the urgent need for safe and effective vaccines, FDA is utilizing its various authorities and expertise to facilitate the expeditious development and availability of vaccines that have met the agency’s rigorous and science-based standards for quality, safety, and effectiveness. Early in a public health crisis, FDA provides clear communication to the pharmaceutical industry pertaining to the scientific data and information needed to ensure development of vaccines and works quickly to provide advice on their proposed development plans and assessment of the data that are generated.

EXHIBIT K

ATTACHMENT D

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION**

ERIC MCARTHUR and JENNY MCARTHUR,
Proceeding on their own behalf and on
Behalf of their minor child, M.M.,

Plaintiffs,

v.

SCOTT BRABRAND, *et. al.*,

Defendants,

Civil Action No.: 3 :21-cv-00317

DECLARATION OF DR. JAYANTA BHATTACHARYA

I, Dr. Jayanta Bhattacharya, declare as follows:

1. I am an adult of sound mind and make this statement voluntarily, based upon my knowledge, education, and experience.

EXPERIENCE & CREDENTIALS

2. I am a former Professor of Medicine and current Professor of Health Policy at Stanford University School of Medicine and a research associate at the National Bureau of Economic Research. I am also Director of Stanford's Center for Demography and Economics of Health and Aging. I hold an M.D. and Ph.D. from Stanford University. I have published 155 scholarly articles in peer-reviewed journals in the fields of medicine, economics, health policy, epidemiology, statistics, law, and public health, among others. My research has been cited in the peer-reviewed scientific literature more than 12,400 times. My curriculum vitae is attached to this declaration as Exhibit A.

3. I have dedicated my professional career to the analysis of health policy, including infectious disease epidemiology and policy, and the safety and efficacy of medical interventions. I have studied extensively and commented publicly on the necessity and safety of vaccine requirements for those who have contracted and recovered from COVID-19 (individuals who have “natural immunity”). I am intimately familiar with the emergent scientific and medical literature on this topic and pertinent government policy responses to the issue both in the United States and abroad.

4. My assessment of vaccine immunity is based on studies related to the efficacy and safety of the one vaccine to receive full approval from the Food and Drug Administration (FDA) and the two vaccines for which the FDA has granted Emergency Use Authorization (EUA) for use in the United States. These include two mRNA-technology vaccines (manufactured by Pfizer-BioNTech and Moderna) and an adenovirus-vector vaccine technology (manufactured by Johnson & Johnson). Of those, the Pfizer vaccine, also known as Comirnaty, has full FDA approval.

5. I have not and will not receive any financial or other compensation to prepare this Declaration or to testify in this case. Nor have I received compensation for preparing declarations or reports or for testifying in *any* other case related to the COVID-19 pandemic or any personal or research funding from any pharmaceutical company. My participation here has been motivated solely by my commitment to public health, just as my involvement in other cases has been.

6. I have been asked to provide my opinion on several matters related to vaccine mandates:

- Whether, based on the current medical and scientific knowledge, immunity after COVID recovery (sometimes referred to as natural immunity) is categorically inferior to vaccine immunity to prevent reinfection and transmission of the SARS-CoV-2 virus;

- Whether, based on the existing medical and scientific understanding of SARS-CoV-2 transmission and recovery, there is any categorical distinction between natural immunity and vaccine immunity;
- Whether there is scientific evidence to support determinations that immunity provided by COVID recovery should not be considered as a reason to be excused from vaccine mandates.

I can summarize my opinions briefly. The scientific evidence strongly indicates that the recovery from COVID disease provides strong and lasting protection against severe disease if reinfected, at least as good and likely better than the protection offered by the COVID vaccines. While the COVID vaccines are effective at protecting vaccinated individuals against severe disease, they provide only short-lasting and limited protection versus infection and disease transmission. Requiring vaccines for COVID recovered patients thus provides only a limited benefit while exposing them to the risks associated with the vaccination.

OPINIONS

I. COVID-19 Infection Fatality Risk

1. SARS-CoV-2, the virus that causes COVID-19 infection, entered human circulation some time in 2019 in China. The virus itself is a member of the coronavirus family of viruses, several of which cause typically mild respiratory symptoms upon infection. The SARS-CoV-2 virus, by contrast, induces a wide range of clinical responses upon infection. These presentations range from entirely asymptomatic infection to mild upper respiratory disease with unusual symptoms like loss of sense of taste and smell, hypoxia, or a deadly viral pneumonia that is the primary cause of death due to SARS-CoV-2 infection.

2. The mortality danger from COVID-19 infection varies substantially by age and a few chronic disease indicators.¹ For most of the population, including the vast majority of children and young adults, COVID-19 infection poses less of a mortality risk than seasonal influenza. By contrast, for older people – especially those with severe comorbid chronic conditions – COVID-19 infection poses a high risk of mortality, on the order of a 5% infection fatality rate.

3. The best evidence on the infection fatality rate from SARS-CoV-2 infection (that is, the fraction of infected people who die due to the infection) comes from seroprevalence studies. The definition of seroprevalence of COVID-19 is the fraction of people in a population who have specific antibodies against SARS-CoV-2 in their bloodstream. A seroprevalence study measures the fraction of a population who have antibodies that are produced specifically by people infected by the SARS-CoV-2 virus. The presence of specific antibodies in blood provides excellent evidence that an individual was previously infected.

4. Seroprevalence studies provide better evidence on the total number of people who have been infected than do case reports or positive reverse transcriptase-polymerase chain reaction (RT-PCR) test counts. PCR tests are the most common type of test used to check whether a person currently has the virus or viral fragments in their body (typically in the nasopharynx). The PCR test should not be used to count the total number of people who have been infected to date in a population. Case reports and PCR test counts both miss infected people who are not identified by the public health authorities or who do not volunteer for RT-PCR testing. That is, they miss people who were infected but recovered from the condition without coming to the attention of public

¹ Public Health England (2020) Disparities in the Risk and Outcomes of COVID-19. August 2020. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/908434/Disparities_in_the_risk_and_outcomes_of_COVID_August_2020_update.pdf

health authorities. Because they ignore unreported infections, fatality rate estimates based on case reports or positive test counts are substantially biased toward reporting a higher fatality rate.

5. According to a meta-analysis² by Dr. John Ioannidis of every seroprevalence study conducted to date of publication with a supporting scientific paper (74 estimates from 61 studies and 51 different localities worldwide), the median infection survival rate—the inverse of the infection fatality rate—from COVID-19 infection is 99.77%. For COVID-19 patients under 70, the meta-analysis finds an infection survival rate of 99.95%. A separate meta-analysis³ by other scientists independent of Dr. Ioannidis' group reaches qualitatively similar conclusions.

6. A study of the seroprevalence of COVID-19 in Geneva, Switzerland (published in *The Lancet*)⁴ provides a detailed age breakdown of the infection survival rate in a preprint companion paper⁵ 99.9984% for patients 5 to 9 years old; 99.99968% for patients 10 to 19 years old; 99.991% for patients 20 to 49 years old; 99.86% for patients 50 to 64 years old; and 94.6% for patients above 65.

7. I estimated the age-specific infection fatality rates from the Santa Clara County seroprevalence study⁶ data (for which I am the senior investigator). The infection survival rate is 100% among people between 0 and 19 years (there were no deaths in Santa Clara in that age range up to that date); 99.987% for people between 20 and 39 years; 99.84% for people between 40 and 69 years; and 98.7% for people above 70 years.

² John P.A. Ioannidis , *The Infection Fatality Rate of COVID- 19 Inferred from Seroprevalence Data*, Bulletin of the World Health Organization BLT 20.265892.

³ Andrew T. Levin, et al., *Assessing the Age Specificity of Infection Fatality Rate for COVID- 19: Meta-Analysis & Public Policy Implications* (Aug. 14,2020)MEDRXIV, <http://bit.ly/3gplolV>.

⁴ Silvia Stringhini, et al., *Seroprevalence of Anti-SARS-CoV-2 IgG Antibodies in Geneva, Switzerland (SEROCoV-POP): A Population Based Study* (June 11, 2020) THE LANCET, <https://bit.ly/3187S13>.

⁵ Francisco Perez-Saez, et al. *Serology- Informed Estimates of SARS-COV-2 Infection Fatality Risk in Geneva, Switzerland* (June 15,2020) OSF PREPRINTS, <http://osf.io/wdbpe/>.

⁶ Eran Bendavid, et al., *COVID- 19 Antibody Seroprevalence in Santa Clara County, California* (April 30,2020) MEDRXIV, <https://bit.ly/2EuLIFK>.

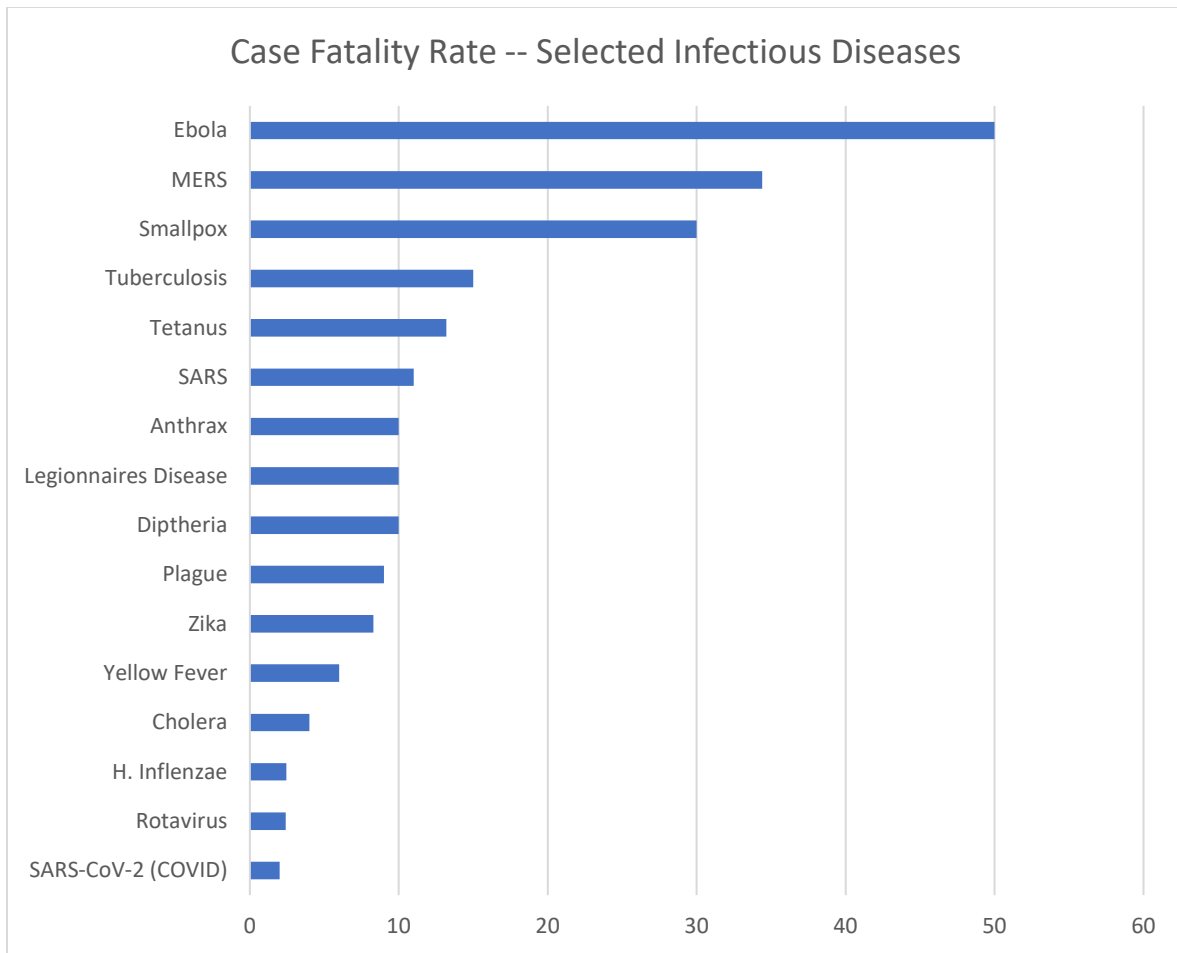
8. Those numbers are consistent with what the US CDC has reported. A US CDC report⁷ found between 6 and 24 times more SARS-CoV-2 infections than cases reported between March and May 2020. Correspondingly, the CDC's estimate of the infection fatality rate for people ages 0-19 years is 0.003%, meaning infected children have a 99.997% survivability rate. For people ages 20-49 years, it was 0.02%, meaning that young adults have a 99.98% survivability rate. For people age 50-69 years, it was 0.5%, meaning this age group has a 99.5% survivability rate. Finally, for people ages 70+ years, it was 5.4%, meaning seniors have a 94.6% survivability rate.

⁸ There is thus no substantial qualitative disagreement about the infection fatality rate reported by the CDC and other sources in the scientific literature. This should come as no surprise since they all rely on seroprevalence studies to estimate infection fatality rates.

9. It is helpful to provide some context for how large the mortality risk is posed by COVID infection relative to the risk posed by other infectious diseases. Since seroprevalence-based mortality estimates are not readily available for every disease, in the figure immediately below, I plot case fatality rates, defined as the number of deaths due to the disease divided by the number of identified or diagnosed cases of that disease. The case fatality rate for SARS-CoV-2 is ~2% (though that number has decreased with the availability of vaccines and effective treatments). By contrast, the case fatality rate for SARS is over five times higher than that, and for MERS, it is 16 times higher than that.

⁷ Fiona P. Havers, et al., *Seroprevalence of Antibodies to SARS-CoV-2 in 10 Sites in the United States, March 23-May 12, 2020* (Jul. 21, 2020) JAMA INTERN MED., <https://bit.ly/3goZUgy>.

⁸ COVID- 19 Pandemic Planning Scenarios, Centers for Disease Control and Prevention, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html>.



10. Perhaps the most important implication of these estimates is that they identify two distinct populations of people who face a very different risk from COVID infection. One segment – the elderly and others with severe chronic disease – faces a higher risk of mortality if infected (especially if unvaccinated). A second segment – typically non-elderly people – face a very low risk of mortality if infected and instead face much greater harm from lockdowns, school closures, and other non-pharmaceutical interventions than from COVID infection itself. The right strategy, then, is focused protection of the vulnerable population by prioritizing them for vaccination while lifting lockdowns and other restrictions on activities for the rest since they cause harm without corresponding benefit for the non-vulnerable. The Great Barrington Declaration, of which I am a primary co-author, describes an alternate policy of focused protection. This policy would lead to

fewer COVID-related deaths and fewer non-COVID-related deaths than universal lockdowns or a strategy that lets the virus rip through the population. My co-authors of this Declaration include Prof. Martin Kulldorff of Harvard University and Prof. Sunetra Gupta of Oxford University. Over 15,000 epidemiologists and public health professionals and 50,000 medical professionals have co-signed the Declaration.⁹

11. The infection fatality rate estimates presented in this section are drawn from data before widespread vaccination in the U.S. and elsewhere. The COVID-19 vaccines approved for use in the U.S. are very effective in substantially reducing the infection fatality rate. According to the US Centers for Disease Control, the mRNA vaccines were 94% effective against COVID-19 hospitalization for patients 65 and older.¹⁰ So, the infection fatality rates that I provide above are overestimated by at least one order of magnitude. Fully vaccinated, non-elderly professors in classrooms face a vanishingly small risk of mortality even if the SARS-CoV-2 virus infects them.

II. Natural Immunity Provides Durable Protection Against Reinfection and Against Severe Outcomes If Reinfected; COVID-19 Vaccines Provide Limited Protection Against Infection but Durable Protection Against Severe Outcomes if Infected.

12. Both vaccine-mediated immunity and natural immunity after recovery from COVID infection provide extensive protection against severe disease from subsequent SARS-CoV-2 infection. There is no reason to presume that vaccine immunity provides a higher level of protection than natural immunity. Since vaccines arrived one year after the disease, there is stronger evidence for long-lasting immunity from natural infection than from the vaccines.

13. Both types of immunity are based on the same basic immunological mechanism—

⁹ Bhattacharya J, Gupta S, Kulldorff M (2020) Great Barrington Declaration. <https://gbdeclaration.org>

¹⁰ Tenforde MW, Olson SM, Self WH, et al. Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Among Hospitalized Adults Aged ≥ 65 Years — United States, January–March 2021. MMWR Morb Mortal Wkly Rep 2021;70:674–679. DOI: <http://dx.doi.org/10.15585/mmwr.mm7018e1>external icon

stimulating the immune system to generate an antibody response. In clinical trials, the efficacy of those vaccines was initially tested by comparing the antibody levels in the blood of vaccinated individuals to those who had natural immunity. Later Phase III studies of the vaccines established 94%+ clinical efficacy of the mRNA vaccines against severe COVID illness.^{11,12} A Phase III trial showed 85% efficacy for the Johnson & Johnson adenovirus-based vaccine against severe disease.¹³

14. Immunologists have identified many immunological mechanisms of immune protection after recovery from infections. Studies have demonstrated prolonged immunity with respect to memory T and B cells,¹⁴ bone marrow plasma cells,¹⁵ spike-specific neutralizing

¹¹ Baden, L. R., El Sahly, H. M., Essink, B., Kotloff, K., Frey, S., Novak, R., Diemert, D., Spector, S. A., Rouphael, N., Creech, C. B., McGettigan, J., Khetan, S., Segall, N., Solis, J., Brosz, A., Fierro, C., Schwartz, H., Neuzil, K., Corey, L., Zaks, T. for the COVE Study Group (2021). Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *The New England Journal of Medicine*, 384(5), 403-416. doi: 10.1056/NEJMoa2035389

¹² Polack, F. P., Thomas, S. J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J. L., Pérez Marc, G., Moreira, E. D., Zerbini, C., Bailey, R., Swanson, K. A., Roychoudhury, S., Koury, K., Li, P., Kalina, W. V., Cooper, D., Frenck, R. W. Jr., Hammitt, L. L., Gruber, W. C. (2020). Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *The New England Journal of Medicine*, 387(27), 2603-2615. doi: 10.1056/NEJMoa2034577

¹³ Sadoff, J., Gray, G., Vandebosch, A., Cárdenas, V., Shukarev, G., Grinsztejn, B., Goepfert, P. A., Truyers, C., Fennema, H., Spiessens, B., Offergeld, K., Scheper, G., Taylor, K. L., Robb, M. L., Treanor, J., Barouch, D. H., Stoddard, J., Ryser, M. F., Marovich, M. A., Douoguih, M. for the ENSEMBLE Study Group. (2021). Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19. *The New England Journal of Medicine*, 384(23), 2187-2201. doi: 10.1056/NEJMoa2101544

¹⁴ Dan, J. M., Mateus, J., Kato, Y., Hastie, K. M., Yu, E. D., Faliti, C. E., Grifoni, A., Ramirez, S. I., Haupt, S., Frazier, A., Nakao, C., Rayaprolu, V., Rawlings, S. A., Peters, B., Krammer, F., Simon, V., Saphire, E. O., Smith, D. M., Weiskopf, D., Crotty, S. (2021). Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. *Science*, 371, 1-13. doi: 10.1126/science.abf4063 (finding that memory T and B cells were present up to eight months after infection, noting that “durable immunity against secondary COVID-19 disease is a possibility in most individuals”).

¹⁵ Turner, J. S., Kim, W., Kalaidina, E., Goss, C. W., Rauseo, A. M., Schmitz, A. J., Hansen, L., Haile, A., Klebert, M. K., Pusic, I., O’Halloran, J. A., Presti, R. M. & Ellebedy, A. H. (2021). SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans. *Nature*,

antibodies,¹⁶ and IgG+ memory B cells¹⁷ following naturally acquired immunity.

15. Multiple extensive, peer-reviewed studies comparing natural and vaccine immunity have now been published. These studies overwhelmingly conclude that natural immunity provides equivalent or greater protection against severe infection than immunity generated by mRNA vaccines (Pfizer and Moderna).

16. Specifically, studies confirm the efficacy of natural immunity against reinfection of COVID-19¹⁸ and show that the vast majority of reinfections are less severe than first-time

595(7867), 421-425. doi: 10.1038/s41586-021-03647-4 (study analyzing bone marrow plasma cells of recovered COVID-19 patients reported durable evidence of antibodies for at least 11 months after infection, describing “robust antigen-specific, long-lived humoral immune response in humans”); Callaway, E. (2021, May 26). Had COVID? You’ll probably make antibodies for a lifetime. *Nature*. <https://www.nature.com/articles/d41586-021-01442-9#:~:text=Many%20people%20who%20have%20been,recovered%20from%20COVID%2D191> (“The study provides evidence that immunity triggered by SARS-CoV-2 infection will be extraordinarily long-lasting” and “people who recover from mild COVID-19 have bone-marrow cells that can churn out antibodies for decades”).

¹⁶ Ripperger, T. J., Uhrlaub, J. E., Watanabe, M., Wong, R., Castaneda, Y., Pizzato, H. A., Thompson, M. R., Bradshaw, C., Weinkauf, C. C., Bime, C., Erickson, H. L., Knox, K., Bixby, B., Parthasarathy, S., Chaudhary, S., Natt, B., Cristan, E., El Aini, T., Rischard, F., Bhattacharya, D. (2020). Orthogonal SARS-CoV-2 serological assays enable surveillance of low-prevalence communities and reveal durable humor immunity. *Immunity*, 53(5), 925-933. doi: 10.1016/j.immuni.2020.10.004 (study finding that spike and neutralizing antibodies remained detectable 5-7 months after recovering from infection).

¹⁷ Cohen, K. W., Linderman, S. L., Moodie, Z., Czartoski, J., Lai, L., Mantus, G., Norwood, C., Nyhoff, L. E., Edara, V. V., Floyd, K., De Rosa, S. C., Ahmed, H., Whaley, R., Patel, S. N., Prigmore, B., Lemos, M. P., Davis, C. W., Furth, S., O’Keefe, J., McElrath, M. J. (2021). Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells. *medRxiv*, Preprint. (study of 254 recovered COVID patients over 8 months “found a predominant broad-based immune memory response” and “sustained IgG+ memory B cell response, which bodes well for rapid antibody response upon virus re-exposure.” “Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients”).

¹⁸ Shrestha, N. K., Burke, P. C., Nowacki, A. S., Terpeluk, P. & Gordon, S. M. (2021). Necessity of COVID-19 vaccination in previously infected individuals. *medRxiv*, Preprint. doi: 10.1101/2021.06.01.21258176 (“not one of the 1359 previously infected subjects who remained unvaccinated had a SARS-CoV-2 infection over the duration of the study” and concluded that those with natural immunity are “unlikely to benefit from COVID-19 vaccination”); Perez, G., Banon,

infections.¹⁹ For example, an Israeli study of approximately 6.4 million individuals demonstrated

T., Gazit, S., Moshe, S. B., Wortsman, J., Grupel, D., Peretz, A., Tov, A. B., Chodick, G., Mizrahi-Reuveni, M., & Patalon, T. (2021). A 1 to 1000 SARS-CoV-2 reinfection proportion in members of a large healthcare provider in Israel: A preliminary report. *medRxiv*, Preprint. doi: 10.1101/2021.03.06.21253051 (Israeli study finding that approximately 1/1000 of participants were reinfectd); Bertollini, R., Chemaitelly, H., Yassine, H. M., Al-Thani, M. H., Al-Khal, A., & Abu-Raddad, L. J. (2021). Associations of vaccination and of prior infection with positive PCR test results for SARS-CoV-2 in airline passengers arriving in Qatar. *JAMA*, 326(2), 185-188. doi: 10.1001/jama.2021.9970 (study of international airline passengers arriving in Qatar found no statistically significant difference in risk of reinfection between those who had been vaccinated and those who had previously been infected); Pilz, S., Chakeri, A., Ioannidis, J. P. A., Richter, L., Theiler-Schwetz, V., Trummer, C., Krause, R., Allerberger, F. (2021). SARS-CoV-2 re-infection risk in Austria. *European Journal of Clinical Investigation*, 51(4), 1-7. doi: 10.1111/eci.13520 (previous SARS-CoV-2 infection reduced the odds of re-infection by 91% compared to first infection in the remaining general population); Breathnach, A. S., Duncan, C. J. A., El Bouzidi, K., Hanrath, A. T., Payne, B. A. I., Randell, P. A., Habibi, M. S., Riley, P. A., Planche, T. D., Busby, J. S., Sudhanva, M., Pallett, S. J. C. & Kelleher, W. P. (2021). Prior COVID-19 protects against reinfection, even in the absence of detectable antibodies. *The Journal of Infection*, 83(2), 237-279. doi: 10.1016/j.jinf.2021.05.024 (0.86% of previously infected population in London became reinfectd); Tarke, A., Sidney, J., Methot, N., Yu, E. D., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., Wang, E., Frazier, A., Ramirez, S. I., Rawlings, S. A., Smith, D. M., da Silva Antunes, R., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A. & Sette, A. (2021). Impact of SARS-CoV-2 variants on the total CD4⁺ and CD8⁺ T cell reactivity in infected or vaccinated individuals, *Cell Reports Medicine* 2(7), 100355 (an examination of the comparative efficacy of T cell responses to existing variants from patients with natural immunity compared to those who received an mRNA vaccine found that the T cell responses of both recovered COVID patients and vaccines were effective at neutralizing mutations found in SARS-CoV-2 variants).

¹⁹ Abu-Raddad, L. J., Chemaitelly, H., Coyle, P., Malek, J. A., Ahmed, A. A., Mohamoud, Y. A., Younuskunju, S., Ayoub, H. H., Kanaani, Z. A., Kuwari, E. A., Butt, A. A., Jeremijenko, A., Kaleeckal, A. H., Latif, A. N., Shaik, R. M., Rahim, H. F. A., Nasrallah, G. K., Yassine, H. M., Al Kuwari, M. G., Al Romaihi, H. E., Al-Thani, M. H., Al Khal, A., Bertollini, R. (2021). SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy. *EClinicalMedicine*, 35, 1-12. doi: 10.1016/j.eclinm.2021.100861 (finding that of 129 reinfections from a cohort of 43,044, only one reinfection was severe, two were moderate, and none were critical or fatal); Hall, V. J., Foulkes, S., Charlett, A., Atti, A., Monk, E. J. M., Simmons, R., Wellington, E., Cole, M. J., Saei, A., Oguti, B., Munro, K., Wallace, S., Kirwan, P. D., Shrotri, M., Vusirikala, A., Rokadiya, S., Kall, M., Zambon, M., Ramsay, M., Hopkins, S. (2021). SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study. *The Lancet*, 397(10283), 1459-1469. doi: 10.1016/S0140-6736(21)00675-9 (finding “a 93% lower risk of COVID-19 symptomatic infection... [which] show[s] equal or higher protection from natural infection, both for symptomatic and asymptomatic infection”); Hanrath, A. T., Payne, B., A., I., & Duncan, C. J. A. (2021). Prior SARS-CoV-2 infection is associated with protection against

that natural immunity provided equivalent if not better protection than vaccine immunity in preventing COVID-19 infection, morbidity, and mortality.²⁰ Of the 187,549 unvaccinated persons with natural immunity in the study, only 894 (0.48%) were reinfected; 38 (0.02%) were hospitalized, 16 (0.008%) were hospitalized with severe disease, and only one died, an individual over 80 years of age. Another study, analyzing data from Italy found that only 0.31% of COVID-recovered patients experienced a reinfection within a year after the initial infection.²¹

17. Variants do not escape the immunity provided by prior infection with the pre-variant virus or vaccination.^{22, 23, 24} This is true of the delta variant as well. In a study of a large population of patients in Israel, *vaccinated* people who had not been previously infected were 13 times higher

symptomatic reinfection. *The Journal of Infection*, 82(4), e29-e30. doi: 10.1016/j.jinf.2020.12.023 (examined reinfection rates in a cohort of healthcare workers and found “no symptomatic reinfections” among those examined and that protection lasted for at least 6 months).

²⁰ Goldberg, Y., Mandel, M., Woodbridge, Y., Fluss, R., Novikov, I., Yaari, R., Ziv, A., Freedman, L., & Huppert, A. (2021). Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel. *medRxiv*, Preprint. doi: 10.1101/2021.04.20.21255670

²¹ Vitale, J., Mumoli, N., Clerici, P., de Paschale, M., Evangelista, I., Cei, M. & Mazzone, A. (2021). Assessment of SARS-CoV-2 reinfection 1 year after primary infection in a population in Lombardy, Italy. *JAMA Internal Medicine*, 181(10), 1407-1409. doi: 10.1001/jamainternmed.2021.2959

²² Tarke, A., Sidney, J., Methot, N., Yu, E. D., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., Wang, E., Frazier, A., Ramirez, S. I., Rawlings, S. A., Smith, D. M., da Silva Antunes, R., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A. & Sette, A. (2021). Impact of SARS-CoV-2 variants on the total CD4⁺ and CD8⁺ T cell reactivity in infected or vaccinated individuals, *Cell Reports Medicine* 2, 100355.

²³ Wu, K., Werner, A. P., Moliva, J. I., Koch, M., Choi, A., Stewart-Jones, G. B. E., Bennett, H., Boyoglu-Barnum, S., Shi, W., Graham, B. S., Carfi, A., Corbett, K. S., Seder, R. A. & Edwards, D. K. (2021). mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants. *bioRxiv*, Preprint. doi: 10.1101/2021.01.25.427948

²⁴ Redd, A. D., Nardin, A., Kared, H., Bloch, E. M., Pekosz, A., Laeyendecker, O., Abel, B., Fehlings, M., Quinn, T. C. & Tobian, A. A. (2021). CD8⁺ T-cell responses in COVID-19 convalescent individuals target conserved epitopes from multiple prominent SARS-CoV-2 circulating variants. *Open Forum Infectious Diseases* 8(7), ofab143.

odds of experiencing a breakthrough infection with the Delta variant than patients who had recovered from COVID but were never vaccinated.²⁵ They had 27 times higher odds of experiencing subsequent symptomatic COVID disease and 7 times higher odds of hospitalization. The design of this Israeli study was particularly strong – it tracked large cohorts of people over time from the time of vaccination or initial infection, and thus carefully distinguished the effect of time since initial exposure or vaccination in estimating its effect estimates. This is important because both vaccine-mediated and infection-mediated protection against subsequent infection diminish with time.

18. In summary, the overwhelming conclusion of the pertinent scientific literature is that natural immunity is at least as effective against subsequent reinfection as even the most effective vaccines.

19. Furthermore, based on such evidence, many scientists have concluded that natural protection against severe disease after COVID recovery is likely to be long-lasting. A survey article published on June 30, 2021, in the *British Medical Journal* concluded, “[t]here is reason to think that immunity could last for several months or a couple of years, at least, given what we know about other viruses and what we have seen so far in terms of antibodies in patients with COVID-19 and in people who have been vaccinated.”²⁶

20. These findings of highly durable natural immunity should not be surprising, as they hold for SARS-CoV-1 (the virus that causes SARS) and other respiratory viruses. According to a

²⁵ Gazit, S., Shlezinger, R., Perez, G., Lotan, R., Peretz, A., Ben-Tov, A., Cohen, D., Muhsen, K., Chodick, G. & Patalon, T. (2021). Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: Reinfections versus breakthrough infections. *medRxiv*, Preprint. doi: 10.1101/2021.08.24.21262415

²⁶ Baraniuk, C. (2021). How long does covid-19 immunity last? *The British Medical Journal*, 373, 1-3. doi: 10.1136/bmj.n1605.

paper published in *Nature* in August 2020, 23 patients who had recovered from SARS-CoV-1 still possess CD4 and CD8 T cells 17 years after infection during the 2003 epidemic.²⁷ A *Nature* paper from 2008 found that 32 people born in 1915 or earlier still retained some level of immunity against the 1918 flu strain—some 90 years later.²⁸

21. In contrast to the concrete findings regarding the robust durability of natural immunity, it is yet unclear in the scientific literature how long-lasting vaccine-induced immunity will be. Notably, the researchers argue that they can best surmise the predicted durability of vaccine immunity by looking at the expected durability of natural immunity.²⁹

22. A study from Qatar by Chemaitelly and colleagues (recently published in the New England Journal of Medicine), which tracked 927,321 individuals for six months after vaccination concluded that the Pfizer vaccine’s “induced protection against infection appears to wane rapidly after its peak right after the second dose, but it persists at a robust level against hospitalization and death for at least six months following the second dose.”³⁰

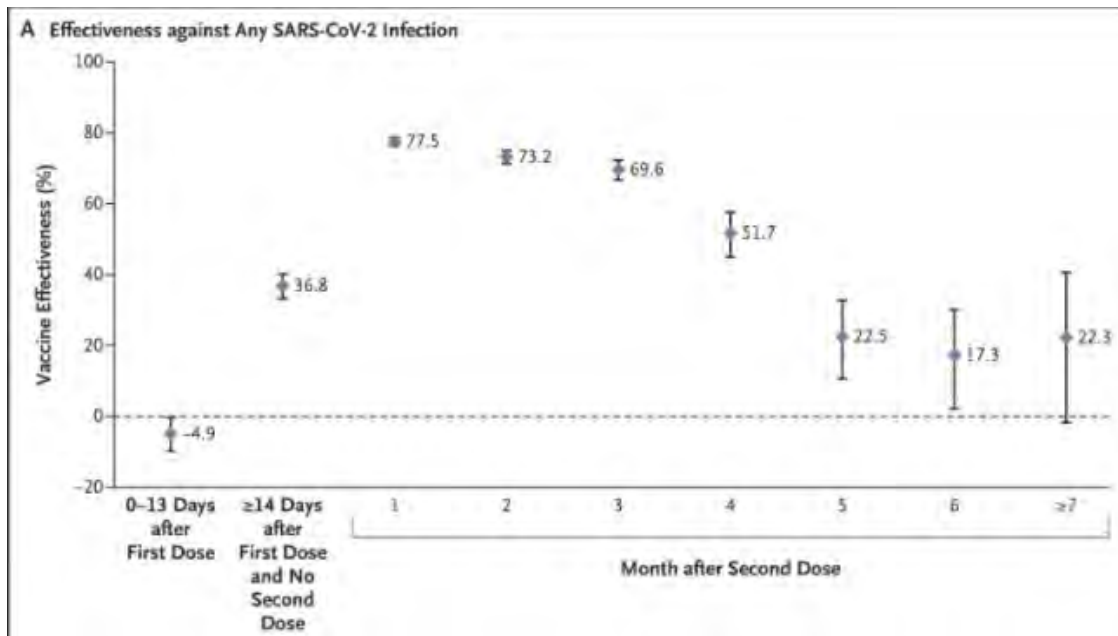
²⁷ Le Bert, N., Tan, A. T., Kunasegaran, K., Tham, C. Y. L., Hafezi, M., Chia, A., Chng, M. H. Y., Lin, M., Tan, N., Linster, M., Chia, W. N., Chen, M. I. C., Wang, L. F., Ooi, E. E., Kalimuddin, S., Tambyah, P. A., Low, J. G. H., Tan, Y. J. & Bertoletti, A. (2020). SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control. *Nature*, 584, 457-462. doi: 10.1038/s41586-020-2550-z

²⁸ Yu, X., Tsibane, T., McGraw, P. A., House, F. S., Keefer, C. J., Hicar, M. D., Tumpey, T. M., Pappas, C., Perrone, L. A., Martinez, O., Stevens, J., Wilson, I. A., Aguilar, P. V., Altschuler, E. L., Basler, C. F., & Crowe Jr., J. E. (2008). Neutralizing antibodies derived from the B cells of 1918 influenza pandemic survivors. *Nature*, 455, 532-536. doi: 10.1038/nature07231

²⁹ Ledford, H. (2021). Six months of COVID vaccines: What 1.7 billion doses have taught scientists. *Nature*, 594(7862), 164-167. doi: 10.1038/d41586-021-01505-x (study notes that “Six months is not much time to collect data on how durable vaccine responses will be. . . . In the meantime some researchers are looking to natural immunity as a guide.”).

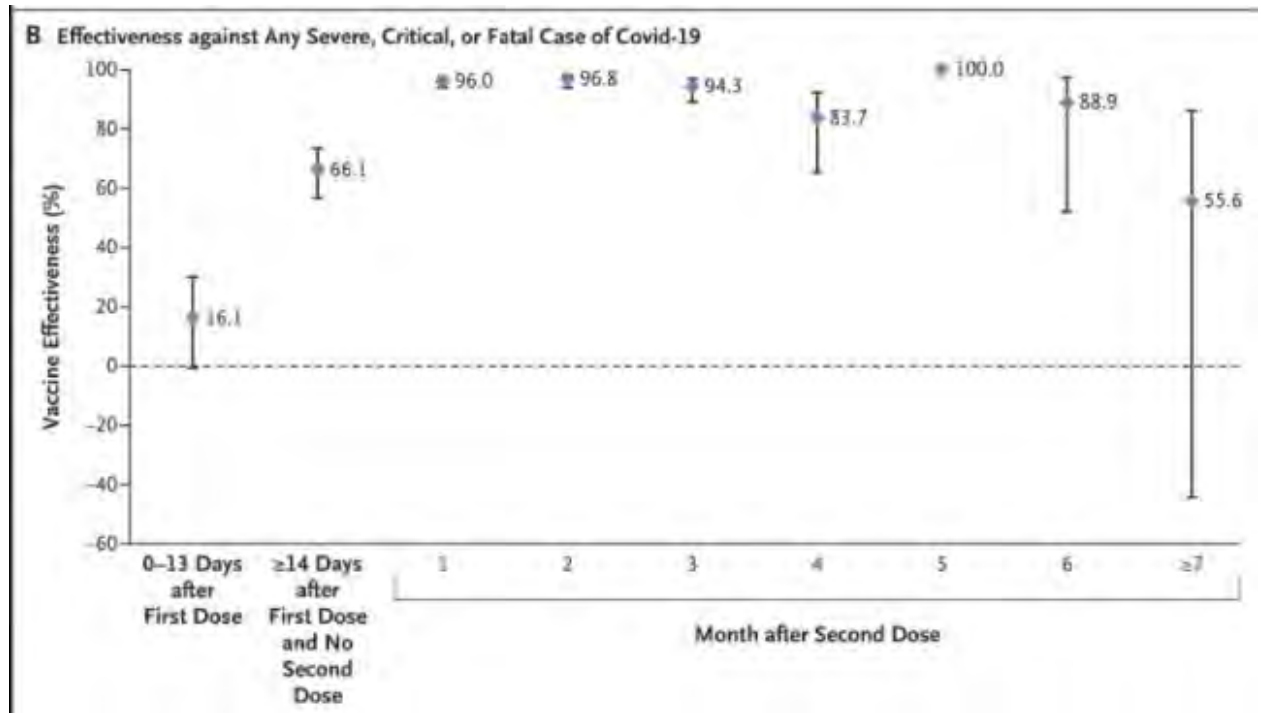
³⁰ Chemaitelly H, Tang P, Hasan MR, AlMukdad S, Yassine HM, Benslimane FM, Al Khatib HA, Coyle P, Ayoub HH, Al Kanaani Z, Al Kuwari E, Jeremijenko A, Kaleeckal AH, Latif AN, Shaik RM, Abdul Rahim HF, Nasrallah GK, Al Kuwari MG, Al Romaihi HE, Butt AA, Al-Thani MH, Al Khal A, Bertollini R, Abu-Raddad LJ. Waning of BNT162b2 Vaccine Protection

23. The key figures from the Qatari study are reproduced immediately below. Panel A shows that vaccine mediated protection against infection peaks at 77.5% one month after the second dose, and then declines to 22.5%, five months after the second dose. According to this result, vaccines effectively protect against infection (and therefore disease spread) for a short period of time after the second dose of the mRNA vaccines.

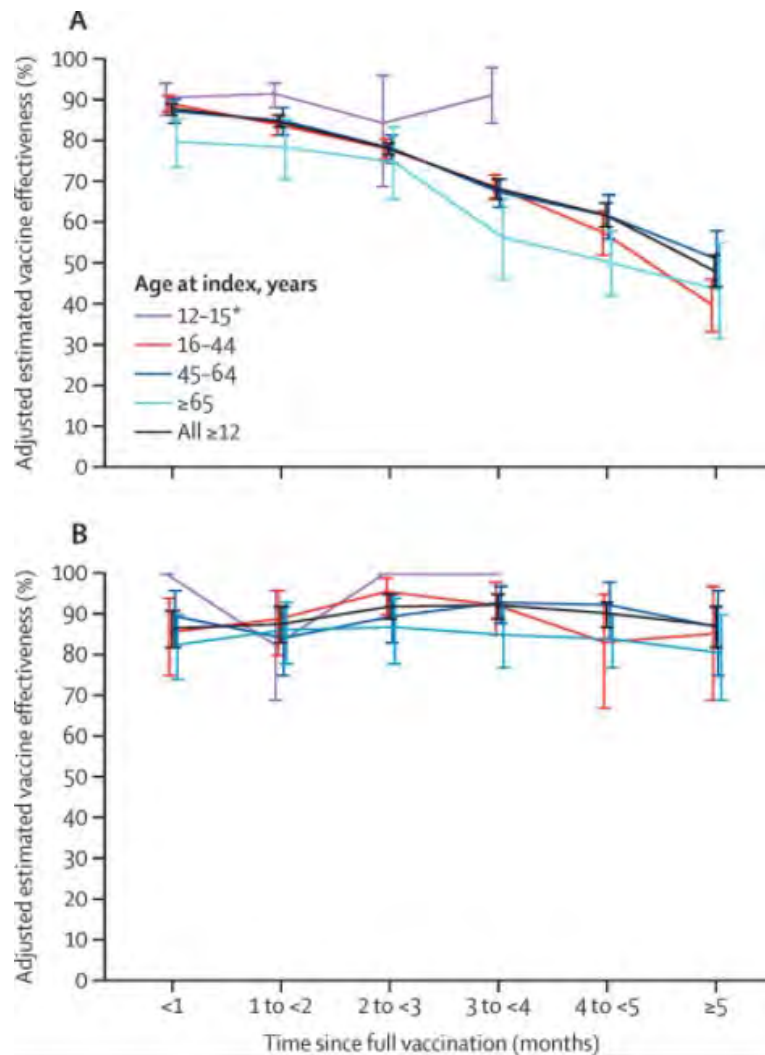


24. On the other hand, Panel B shows that protection versus severe disease is long lasting after vaccination—even though the person will no longer be fully protected against infection and, presumably, disease spread. At 6 months after the second dose, the vaccine remains 88.9% efficacious versus severe disease. While it appears to dip at 7 months to 55.6% efficacy, the confidence interval is so wide that it is consistent with no decrease whatsoever even after 7 months.

against SARS-CoV-2 Infection in Qatar. N Engl J Med. 2021 Oct 6;NEJMoa2114114. doi: 10.1056/NEJMoa2114114. Epub ahead of print. PMID: 34614327; PMCID: PMC8522799.



25. The Qatari study is no outlier. A large study in California tracked the infection rates for nearly 5 million patients vaccinated with two doses of the Pfizer mRNA vaccine. The study tracked both SARS-CoV-2 infections as well as COVID-19 related hospitalizations. The figure immediately below plots the trend in vaccine efficacy over time for different age groups in the population cohort. **Panel A** on the right plots effectiveness versus SARS-CoV-2 infections.³¹ Though the drop in effectiveness is not as

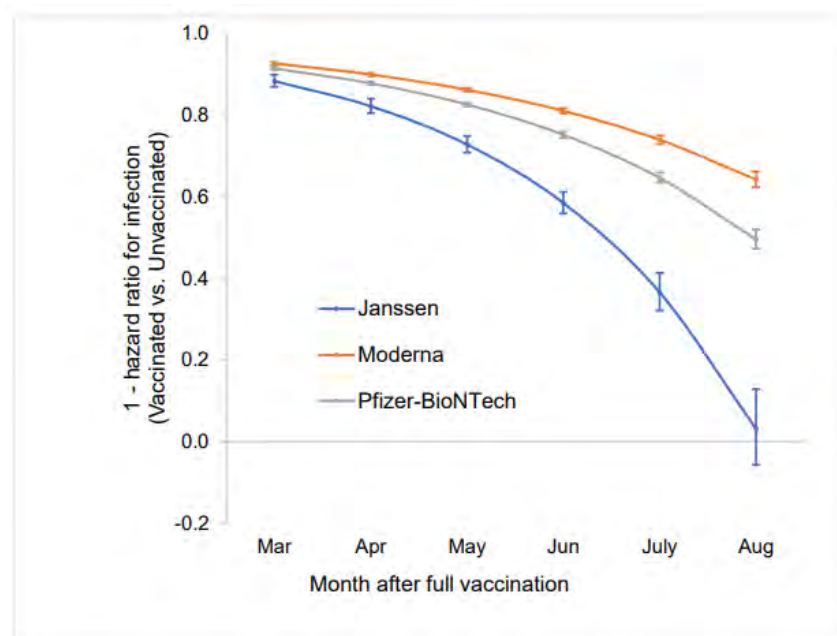


steep as in the Qatari study, there is nevertheless a sharp drop. While in the first month, vaccine effectiveness is near 90% for all age-groups, by month 5, it drops to nearly 50% for all the groups. By contrast, **Panel B** plots vaccine efficacy versus hospitalizations. It remains high with no decline over time –near 90% throughout the period. The vaccine provides durable private protection versus

³¹ Tartof SY, Slezak JM, Fischer H, Hong V, Ackerson BK, Ranasinghe ON, Frankland TB, Ogun OA, Zamparo JM, Gray S, Valluri SR, Pan K, Angulo FJ, Jodar L, McLaughlin JM. Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study. *Lancet*. 2021 Oct 16;398(10309):1407-1416. doi: 10.1016/S0140-6736(21)02183-8. Epub 2021 Oct 4. PMID: 34619098; PMCID: PMC8489881.

severe disease, but declining protection versus infection (and hence transmission).

26. Another recent study tracked 620,000 vaccinated U.S. veterans to measure breakthrough infections for the three vaccines in common use in the U.S.³² Like the other studies, the authors of the study found a sharp decline in vaccine effectiveness versus infection. Five months after vaccination, the effectiveness of the J&J vaccine dropped from ~90% to less than 10%; the Pfizer vaccine dropped from ~90% to ~50%; and the Moderna dropped from ~90% to ~65%. The figure on this page tracks the decline in effectiveness of the vaccines against infection over time documented in this study. This study corroborates yet another study that documented declining vaccine efficacy in the first three months after vaccination against disease transmission in the era of the Delta variant.³³



³² Cohn BA, Cirillo PM, Murphy CC, et al. Breakthrough SARS-CoV-2 Infections in 620,000 U.S. Veterans, February 1, 2021 to August 13, 2021. medRxiv. October 14, 2021. <https://doi.org/10.1101/2021.10.13.21264966>;

³³ Eyre, D. W., Taylor, D., Purver, M., Chapman, D., Fowler, T., Pouwels, K. B., Walker, A. S. & Peto, T. E. A. (2021). The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. medRxiv, Preprint. doi: 10.1101/2021.09.28.21264260

27. Yet another study conducted in Wisconsin confirmed that vaccinated individuals can shed infectious SARS-CoV-2 viral particles.³⁴ The authors analyzed nasopharyngeal samples to check whether patients showed evidence of infectious viral particles. They found that vaccinated individuals were at least as likely as unvaccinated individuals to be shedding live virus. They concluded:

Combined with other studies these data indicate that vaccinated and unvaccinated individuals infected with the Delta variant might transmit infection. Importantly, we show that infectious SARS-CoV-2 is frequently found even in vaccinated persons.

28. A recent study in the U.K. during its wave of Delta COVID cases compared the likelihood of a vaccinated individual passing on the disease to someone within their same household relative to unvaccinated patients.³⁵ This study tracked these groups of patients over time to the point they tested positive for COVID. At that point, study investigators measured levels of the SARS-CoV-2 virus in the patients, and observed whether the patients passed on the disease to other household members. The authors find that while vaccination does reduce the fraction of time that a patient passes the disease on to household members from 38% [95% confidence interval: 24-53] to 25% [95% confidence interval: 18-33], there was no statistically significant difference ($p=0.17$). They conclude:

Vaccination reduces the risk of delta variant infection and accelerates viral clearance. Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load

³⁴ Riemersma, K. K., Grogan, B. E., Kita-Yarbro, A., Halfmann, P. J., Segaloff, H. E., Kocharian, A., Florek, K. R., Westergaard, R., Bateman, A., Jeppson, G. E., Kawaoka, Y., O'Connor, D. H., Friedrich, T. C., & Grande, K. M. (2021). Shedding of infectious SARS-CoV-2 despite vaccination. *medRxiv*, Preprint. doi: 10.1101/2021.07.31.21261387

³⁵ Singanayagam A, Hakki S, Dunning J, et al. Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study [published online ahead of print, 2021 Oct 29]. *Lancet Infect Dis*. 2021;doi:10.1016/S1473-3099(21)00648-4

similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts.

29. The CDC recognizes the importance of natural immunity in its updated science brief analyzing the difference in immunity from infection-induced and vaccine-induced immunity.³⁶ The CDC noted that “confirmed SARS-CoV-2 infection decreased risk of subsequent infection by 80–93% for at least 6–9 months,” with some studies showing “slightly higher protective effects (89-93%).” It also noted that “researchers have predicted that the immune response following infection would continue to provide at least 50% protection against reinfection for 1–2 years following initial infection with SARS-CoV-2 or vaccination. This would be similar to what is observed with seasonal coronaviruses.”

30. The CDC science brief does claim that vaccine-induced immunity is stronger than immunity from natural infection.³⁷ This study the CDC relies on to support this claim is not determinative for several reasons.³⁸ First, its result is contrary to the weight of other evidence, as set forth above. Second, the study compared hospitalization of those infected—and had natural immunity—90-225 days after their infection while against those who had completed their RNA vaccine regime 45-213 days before reinfection. Because immunity—regardless of how gained—waned over time, the failure to adequately compare like periods means that the study’s conclusions are biased in favor of vaccine-induced immunity. Indeed, the study admits this weakness. Third, the study design itself does not permit it to address the critical question of interest – whether

³⁶ CDC, Science Brief: SARS-CoV-2 Infection-Induced and Vaccine-Induced Immunity (updated Oct. 29, 2021), https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html#anchor_1635539757101

³⁷ *Id.*

³⁸ Bozio CH, Grannis SJ, Naleway AL, et al. Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19–Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity — Nine States, January–September 2021. *MMWR Morb Mortal Wkly Rep.* ePub: 29 October 2021.

COVID-recovery without vaccination or vaccination without COVID-recovery provides stronger protection against COVID-related hospitalization. The study analyzes only patients who are already in the hospital. To obtain an accurate answer to the question of interest, it would need to include and analyze patients before entering the hospital. As it is, the study implicitly and incorrectly assumes that the set of hospitalized patients with COVID-like symptoms is representative of the population at large, which is untrue.

31. In summary, the evidence to date strongly suggests that while vaccines—like natural immunity—protect against severe disease, they, unlike natural immunity, provide only short-lasting protection against subsequent infection and disease spread. In short, there is no medical or scientific reason to believe that vaccine immunity will prove longer-lasting immunity than natural immunity, much less more durable immunity.

III. The CDC's Recommendation for Vaccination of Recovered COVID Patients Applies with Equal Force to Those Who Have Been Previously Vaccinated, Whose Protection Against Infection Wanes Within a Few Months After Vaccination.

32. The CDC, in the Frequently Asked Questions (FAQ) section of its website encouraging vaccination, provides the following advice to previously recovered patients:³⁹

Yes, you should be vaccinated regardless of whether you already had COVID-19. That's because experts do not yet know how long you are protected from getting sick again after recovering from COVID-19. Even if you have already recovered from COVID-19, it is possible—although rare—that you could be infected with the virus that causes COVID-19 again. Studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19. Learn more about why getting vaccinated is a safer way to build protection than getting infected.

33. The text of this advice by the CDC does not address any of the scientific evidence included here about the lack of necessity for recovered COVID patients to be vaccinated. While it is true that I do not know how long natural immunity after recovery lasts, the immunological evidence to date suggests that protection against disease will last for years.⁴⁰ Uncertainty over the longevity of immunity after recovery is a specious reason for not exempting COVID-recovered patients from vaccination mandates, since the same can be said about vaccine mediated immunity. I do not know how long it will last either, and there is no reason to believe it provides longer lasting or more complete immunity than recovery from COVID.

34. Similarly, just as reinfections are possible though rare after COVID recovery, breakthrough infections are possible after vaccination, as the CDC's team investigating vaccine

³⁹ Centers for Disease Control and Prevention. (2021, September 28). Frequently asked questions about COVID-19 vaccination. Retrieved October 1, 2019 from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>

⁴⁰ Patel, N. V. (2021, January 6). *Covid-19 immunity likely lasts for years*. MIT Technology Review. <https://www.technologyreview.com/2021/01/06/1015822/covid-19-immunity-likely-lasts-for-years/>

breakthrough infections itself recognizes.⁴¹ On the same CDC FAQ webpage I cite above,⁴² the CDC writes about vaccine-mediated immunity, “We don’t know how long protection lasts for those who are vaccinated.”

35. The CDC’s main concern in this FAQ seems to be to help people understand that it is safer to attain immunity against SARS-CoV-2 infection via vaccination rather than via infection. This is a point not in dispute. Rather, the question is whether someone who *already* has been infected and recovered will benefit on net from the additional protection provided by vaccination. On this point, the CDC’s statement in the FAQ is irrelevant. Here again, the possibility of reinfection does not alter the conclusion that, especially for those who have already recovered from COVID, accommodations can be allowed without threatening public safety.

⁴¹ CDC COVID-19 Vaccine Breakthrough Case Investigations Team. (2021). COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021. *Morbidity and Mortality Weekly Report (MMWR)*, 70(21), 792-793. doi: <http://dx.doi.org/10.15585/mmwr.mm7021e3>

⁴² Centers for Disease Control and Prevention. (2021, September 28). Frequently asked questions about COVID-19 vaccination. Retrieved October 1, 2021 from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>

IV. Conclusion

36. Based on the scientific evidence to date, those who have recovered from a SARS-CoV-2 infection possess immunity as robust and durable (or more) as that acquired through vaccination. The existing clinical literature overwhelmingly indicates that the protection afforded to the individual and community from natural immunity is as effective and durable as the efficacy levels of the most effective vaccines to date.

37. Based on my analysis of the existing medical and scientific literature, any policy regarding vaccination that does not recognize natural immunity is irrational, arbitrary, and counterproductive to community health.⁴³

38. Indeed, now that every American adult, teenager, and child five and above has free access to the vaccines, the case for a vaccine mandate is weaker than it once was. Since the successful vaccination campaign already protects the vulnerable population, the unvaccinated—especially recovered COVID patients—pose a vanishingly small threat to the vaccinated. They are protected by an effective vaccine that dramatically reduces the likelihood of hospitalization or death after infections to near zero. At the same time, natural immunity provides benefits that are at least as strong and may well be stronger than those from vaccines.

39. I declare under penalty of perjury under the laws of the United States of America that, to the best of my knowledge, the foregoing is true and correct.

⁴³ Bhattacharya, J., Gupta, S. & Kulldorff, M. (2021, June 4). *The beauty of vaccines and natural immunity*. Smerconish Newsletter. <https://www.smerconish.com/exclusive-content/the-beauty-of-vaccines-and-natural-immunity>

Executed this 20th day of December, 2021, at Stanford, California.

Respectfully submitted,

A handwritten signature in black ink, consisting of a series of loops and strokes, likely representing the name Jay Bhattacharya.

Dr. Jay Bhattacharya, MD, Ph.D.
Professor of Health Policy
Stanford University

Exhibit L

Title page

Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections

Sivan Gazit, MD MA^{1,2*}; Roei Shlezinger, BA¹; Galit Perez, MN MA²; Roni Lotan, PhD²; Asaf Peretz, MD^{1,3}; Amir Ben-Tov, MD^{1,4}; Dani Cohen, PhD⁴; Khitam Muhsen, PhD⁴; Gabriel Chodick, PhD MHA^{2,4}; Tal Patalon, MD^{1,2}

*Corresponding author.

¹Kahn Sagol Maccabi (KSM) Research & Innovation Center, Maccabi Healthcare Services, Tel Aviv, 68125, Israel.

²Maccabitech Institute for Research and Innovation, Maccabi Healthcare Services, Israel.

³Internal Medicine COVID-19 Ward, Samson Assuta Ashdod University Hospital, Ashdod Israel.

⁴Sackler Faculty of Medicine, School of Public Health, Tel Aviv University, Tel Aviv, Israel.

The authors declare they have no conflict of interest.

Funding: There was no external funding for the project.

Corresponding author: Sivan Gazit, gazit_s@mac.org.il, 27 HaMared street, Tel Aviv, 68125, Israel

Abstract

Background:

Reports of waning vaccine-induced immunity against COVID-19 have begun to surface. With that, the comparable long-term protection conferred by previous infection with SARS-CoV-2 remains unclear.

Methods:

We conducted a retrospective observational study comparing three groups: (1)SARS-CoV-2-naïve individuals who received a two-dose regimen of the BioNTech/Pfizer mRNA BNT162b2 vaccine, (2)previously infected individuals who have not been vaccinated, and (3)previously infected *and* single dose vaccinated individuals. Three multivariate logistic regression models were applied. In all models we evaluated four outcomes: SARS-CoV-2 infection, symptomatic disease, COVID-19-related hospitalization and death. The follow-up period of June 1 to August 14, 2021, when the Delta variant was dominant in Israel.

Results:

SARS-CoV-2-naïve vaccinees had a 13.06-fold (95% CI, 8.08 to 21.11) increased risk for breakthrough infection with the Delta variant compared to those previously infected, when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant ($P<0.001$) for symptomatic disease as well. When allowing the infection to occur at any time before vaccination (from March 2020 to February 2021), evidence of waning natural immunity was demonstrated, though SARS-CoV-2 naïve vaccinees had a 5.96-fold (95% CI, 4.85 to

7.33) increased risk for breakthrough infection and a 7.13-fold (95% CI, 5.51 to 9.21) increased risk for symptomatic disease. SARS-CoV-2-naïve vaccinees were also at a greater risk for COVID-19-related-hospitalizations compared to those that were previously infected.

Conclusions:

This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity. Individuals who were both previously infected with SARS-CoV-2 and given a single dose of the vaccine gained additional protection against the Delta variant.

Introduction

The heavy toll that SARS-CoV-2 infection has been taking on global health and

healthcare resources has created an urgent need to estimate which part of the

population is protected against COVID-19 at a given time in order to set healthcare

policies such as lockdowns and to assess the possibility of herd immunity.

To date, there is still no evidence-based, long-term correlate of protection¹. This lack of correlate of protection has led to different approaches in terms of vaccine resource allocation, namely the need for vaccine administration in recovered patients, the need for booster shots in previously vaccinated individuals or the need to vaccinate low-risk populations, potentially previously exposed.

The short-term effectiveness of a two-dose regimen of the BioNTech/Pfizer

BNT162b2 mRNA COVID-19 vaccine was demonstrated in clinical trials² and in

observational settings^{3,4}. However, long term effectiveness across different variants is still unknown, though reports of waning immunity are beginning to surface, not merely in terms of antibody dynamics over time⁵⁻⁷, but in real-world settings as well⁸.

Alongside the question of long-term protection provided by the vaccine, the degree and duration to which previous infection with SARS-CoV-2 affords protection against repeated infection also remains unclear. Apart from the paucity of studies examining long-term protection against reinfection⁹, there is a challenge in defining reinfection as opposed to prolonged viral shedding¹⁰. While clear-cut cases exist, namely two separate clinical events with two distinct sequenced viruses, relying solely on these cases will likely result in an under-estimation of the incidence of reinfection.

Different criteria based on more widely-available information have been suggested¹¹, the Centers for Disease Control and Prevention's (CDC) guidelines refer to two positive SARS-CoV-2 polymerase chain reaction (PCR) test results at least 90 days

apart.¹² Using similar criteria, population-based studies demonstrated natural immunity^{13,14} with no signs of waning immunity for at least 7 months, though protection was lower for those aged 65 or older⁹.

The Delta (B.1.617.2) Variant of Concern (VOC), initially identified in India and today globally prevalent, has been the dominant strain in Israel since June 2021. The recent surge of cases in Israel¹⁵, one of the first countries to embark on a nationwide vaccination campaign (mostly with the BioNTech/Pfizer BNT162b2 vaccine), has raised concerns about vaccine effectiveness against the Delta variant, including official reports of decreased protection¹⁶. Concomitantly, studies have demonstrated only mild differences in short-term vaccine effectiveness¹⁷ against the Delta variant, as well as substantial antibody response¹⁸. Apart from the variant, the new surge was also explained by the correlation found between time-from-vaccine and breakthrough infection rates, as early vaccinees were demonstrated to be significantly more at risk than late vaccinees⁸. Now, when sufficient time has passed since both the beginning of the pandemic and the deployment of the vaccine, we can examine the long-term protection of natural immunity compared to vaccine-induced immunity.

To this end, we compared the incidence rates of breakthrough infections to the incidence rates of reinfection, leveraging the centralized computerized database of Maccabi Healthcare Services (MHS), Israel's second largest Health Maintenance Organization.

Methods

Study design and population

A retrospective cohort study was conducted, leveraging data from MHS' centralized computerized database. The study population included MHS members aged 16 or older who were vaccinated prior to February 28, 2021, who had a documented SARS-CoV-2 infection by February 28, 2021, or who had both a documented SARS-CoV-2 infection by February 28, 2021 *and* received one dose of the vaccine by May 25, 2021, at least 7 days before the study period. On March 2, 2021, The Israeli Ministry of Health revised its guidelines and allowed previously SARS-CoV-2 infected individuals to receive one dose of the vaccine, after a minimum 3-month-interval from the date of infection

Data Sources

Anonymized Electronic Medical Records (EMRs) were retrieved from MHS' centralized computerized database for the study period of March 1, 2020 to August 14, 2021.

MHS is a 2.5-million-member, state-mandated, non-for-profit, second largest health fund in Israel, which covers 26% of the population and provides a representative sample of the Israeli population. Membership in one of the four national health funds is mandatory, whereas all citizens must freely choose one of four funds, which are prohibited by law from denying membership to any resident. MHS has maintained a centralized database of EMRs for three decades, with less than 1% disengagement rate among its members, allowing for a comprehensive longitudinal medical follow-up. The centralized dataset includes extensive demographic data, clinical measurements, outpatient and hospital diagnoses and procedures, medications

dispensed, imaging performed and comprehensive laboratory data from a single central laboratory.

Data extraction and definition of the study variables

COVID-19-related data

COVID-19-related information was captured as well, including dates of the first and second dose of the vaccine and results of any polymerase chain reaction (PCR) tests for SARS-CoV-2, given that all such tests are recorded centrally. Records of COVID-19-related hospitalizations were retrieved as well, and COVID-19-related mortality was screened for. Additionally, information about COVID-19-related symptoms was extracted from EMRs, where they were recorded by the primary care physician or a certified nurse who conducted in-person or phone visits with each infected individual.

Exposure variable: study groups

The eligible study population was divided into three groups: (1) fully vaccinated and SARS-CoV-2-naïve individuals, namely MHS members who received two doses of the BioNTech/Pfizer mRNA BNT162b2 vaccine by February 28, 2021, did not receive the third dose by the end of the study period and did not have a positive PCR test result by June 1, 2021; (2) unvaccinated previously infected individuals, namely MHS members who had a positive SARS-CoV-2 PCR test recorded by February 28, 2021 and who had not been vaccinated by the end of the study period; (3) previously infected *and* vaccinated individuals, including individuals who had a positive SARS-CoV-2 PCR test by February 28, 2021 and received one dose of the vaccine by May 25, 2021, at least 7 days before the study period. The fully vaccinated group was the comparison (reference) group in our study. Groups 2 and 3, were matched to the

comparison group 1 in a 1:1 ratio based on age, sex and residential socioeconomic status.

Dependent variables

We evaluated four SARS-CoV-2-related outcomes, or second events: documented RT-PCR confirmed SARS-CoV-2 infection, COVID-19, COVID-19-related hospitalization and death. Outcomes were evaluated during the follow-up period of June 1 to August 14, 2021, the date of analysis, corresponding to the time in which the Delta variant became dominant in Israel.

Covariates

Individual-level data of the study population included patient demographics, namely age, sex, socioeconomic status (SES) and a coded geographical statistical area (GSA, assigned by Israel's National Bureau of Statistics, corresponds to neighborhoods and is the smallest geostatistical unit of the Israeli census). The SES is measured on a scale from 1 (lowest) to 10, and the index is based on several parameters, including household income, educational qualifications, household crowding and car ownership. Data were also collected on last documented body mass index (BMI) and information about chronic diseases from MHS' automated registries, including cardiovascular diseases¹⁹, hypertension²⁰, diabetes²¹, chronic kidney disease²², chronic obstructive pulmonary disease, immunocompromised conditions, and cancer from the National Cancer Registry²³.

Statistical analysis

Two multivariate logistic regression models were applied that evaluated the four aforementioned SARS-CoV-2-related outcomes as dependent variables, while the study groups were the main independent variables.

Model 1– previously infected vs. vaccinated individuals, with matching for time of first event

In model 1, we examined natural immunity and vaccine-induced immunity by comparing the likelihood of SARS-CoV-2-related outcomes between previously infected individuals who have never been vaccinated and fully vaccinated SARS-CoV-2-naïve individuals. These groups were matched in a 1:1 ratio by age, sex, GSA and time of first event. The first event (the preliminary exposure) was either the time of administration of the second dose of the vaccine *or* the time of documented infection with SARS-CoV-2 (a positive RT-PCR test result), both occurring between January 1, 2021 and February 28, 2021. Thereby, we matched the “immune activation” time of both groups, examining the long-term protection conferred when vaccination or infection occurred within the same time period. The three-month interval between the first event and the second event was implemented in order to capture reinfections (as opposed to prolonged viral shedding) by following the 90-day guideline of the CDC.

Model 2

In model 2, we compared the SARS-CoV-2 naïve vaccinees to unvaccinated previously infected individuals while intentionally *not* matching the time of the first event (i.e., either vaccination or infection), in order to compare vaccine-induced immunity to natural immunity, regardless of time of infection. Therefore, matching

was done in a 1:1 ratio based on age, sex and GSA alone. Similar to the model 1, either event (vaccination or infection) had to occur by February 28, to allow for the 90-day interval. The four SARS-CoV-2 study outcomes were the same for this model, evaluated during the same follow-up period.

Model 3

Model 3 examined previously infected individuals vs. previously-infected-and-once-vaccinated individuals, using “natural immunity” as the baseline group. We matched the groups in a 1:1 ratio based on age, sex and GSA. SARS-CoV-2 outcomes were the same, evaluated during the same follow-up period.

In all three models, we estimated natural immunity vs. vaccine-induced immunity for each SARS-CoV-2-related outcome, by applying logistic regression to calculate the odds ratio (OR) between the two groups in each model, with associated 95% confidence intervals (CIs). Results were then adjusted for underlying comorbidities, including obesity, cardiovascular diseases, diabetes, hypertension, chronic kidney disease, cancer and immunosuppression conditions.

Analyses were performed using Python version 3.73 with the stats model package.

$P < 0.05$ was considered statistically significant.

Ethics declaration

This study was approved by the MHS (Maccabi Healthcare Services) Institutional Review Board (IRB). Due to the retrospective design of the study, informed consent was waived by the IRB, and all identifying details of the participants were removed before computational analysis.

Data availability statement

According to the Israel Ministry of Health regulations, individual-level data cannot be shared openly. Specific requests for remote access to de-identified community-level data should be directed to KSM, Maccabi Healthcare Services Research and Innovation Center.

Code availability

Specific requests for remote access to the code used for data analysis should be referred to KSM, Maccabi Healthcare Services Research and Innovation Center.

Results

Overall, 673,676 MHS members 16 years and older were eligible for the study group of fully vaccinated SARS-CoV-2-naïve individuals; 62,883 were eligible for the study group of unvaccinated previously infected individuals and 42,099 individuals were eligible for the study group of previously infected and single-dose vaccinees.

Model 1 – previously infected vs. vaccinated individuals, with matching for time of first event

In model 1, we matched 16,215 persons in each group. Overall, demographic characteristics were similar between the groups, with some differences in their comorbidity profile (Table 1a).

During the follow-up period, 257 cases of SARS-CoV-2 infection were recorded, of which 238 occurred in the vaccinated group (breakthrough infections) and 19 in the previously infected group (reinfections). After adjusting for comorbidities, we found a statistically significant 13.06-fold (95% CI, 8.08 to 21.11) increased risk for breakthrough infection as opposed to reinfection ($P<0.001$). Apart from age ≥ 60 years, there was no statistical evidence that any of the assessed comorbidities significantly affected the risk of an infection during the follow-up period (Table 2a).

As for symptomatic SARS-COV-2 infections during the follow-up period, 199 cases were recorded, 191 of which were in the vaccinated group and 8 in the previously infected group. Symptoms for all analyses were recorded in the central database within 5 days of the positive RT-PCR test for 90% of the patients, and included chiefly fever, cough, breathing difficulties, diarrhea, loss of taste or smell, myalgia, weakness, headache and sore throat. After adjusting for comorbidities, we found a 27.02-fold risk (95% CI, 12.7 to 57.5) for symptomatic breakthrough infection as

opposed to symptomatic reinfection ($P<0.001$) (Table 2b). None of the covariates were significant, except for age ≥ 60 years.

Nine cases of COVID-19-related hospitalizations were recorded, 8 of which were in the vaccinated group and 1 in the previously infected group (Table S1). No COVID-19-related deaths were recorded in our cohorts.

Model 2 –previously infected vs. vaccinated individuals, without matching for time of first event

In model 2, we matched 46,035 persons in each of the groups (previously infected vs. vaccinated). Baseline characteristics of the groups are presented in Table 1a. Figure 1 demonstrates the timely distribution of the first infection in reinfected individuals.

When comparing the vaccinated individuals to those previously infected at any time (including during 2020), we found that throughout the follow-up period, 748 cases of SARS-CoV-2 infection were recorded, 640 of which were in the vaccinated group (breakthrough infections) and 108 in the previously infected group (reinfections).

After adjusting for comorbidities, a 5.96-fold increased risk (95% CI, 4.85 to 7.33) increased risk for breakthrough infection as opposed to reinfection could be observed ($P<0.001$) (Table 3a). Apart from SES level and age ≥ 60 , that remained significant in this model as well, there was no statistical evidence that any of the comorbidities significantly affected the risk of an infection.

Overall, 552 symptomatic cases of SARS-CoV-2 were recorded, 484 in the vaccinated group and 68 in the previously infected group. There was a 7.13-fold (95% CI, 5.51 to 9.21) increased risk for symptomatic breakthrough infection than symptomatic reinfection (Table 3b). COVID-19 related hospitalizations occurred in 4 and 21 of the reinfection and breakthrough infection groups, respectively. Vaccinated

individuals had a 6.7-fold (95% CI, 1.99 to 22.56) increased to be admitted compared to recovered individuals. Being 60 years of age or older significantly increased the risk of COVID-19-related hospitalizations (Table S2). No COVID-19-related deaths were recorded.

Model 3 - previously infected vs. vaccinated and previously infected individuals

In model 3, we matched 14,029 persons. Baseline characteristics of the groups are presented in Table 1b. Examining previously infected individuals to those who were both previously infected and received a single dose of the vaccine, we found that the latter group had a significant 0.53-fold (95% CI, 0.3 to 0.92) (Table 4a) decreased risk for reinfection, as 20 had a positive RT-PCR test, compared to 37 in the previously infected and unvaccinated group. Symptomatic disease was present in 16 single dose vaccinees and in 23 of their unvaccinated counterparts. One COVID-19-related hospitalization occurred in the unvaccinated previously infected group. No COVID-19-related mortality was recorded.

We conducted a further sub-analysis, compelling the single-dose vaccine to be administered *after* the positive RT-PCR test. This subset represented 81% of the previously-infected-and-vaccinated study group. When performing this analysis, we found a similar, though not significant, trend of decreased risk of reinfection, with an OR of 0.68 (95% CI, 0.38 to 1.21, *P*-value=0.188).

Discussion

This is the largest real-world observational study comparing natural immunity, gained through previous SARS-CoV-2 infection, to vaccine-induced immunity, afforded by the BNT162b2 mRNA vaccine. Our large cohort, enabled by Israel's rapid rollout of the mass-vaccination campaign, allowed us to investigate the risk for additional infection – either a breakthrough infection in vaccinated individuals or reinfection in previously infected ones – over a longer period than thus far described.

Our analysis demonstrates that SARS-CoV-2-naïve vaccinees had a 13.06-fold increased risk for breakthrough infection with the Delta variant compared to those previously infected, when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant for a symptomatic disease as well.

Broadening the research question to examine the extent of the phenomenon, we allowed the infection to occur at any time between March 2020 to February 2021 (when different variants were dominant in Israel), compared to vaccination only in January and February 2021. Although the results could suggest waning natural immunity against the Delta variant, those vaccinated are still at a 5.96-fold increased risk for breakthrough infection and at a 7.13-fold increased risk for symptomatic disease compared to those previously infected. SARS-CoV-2-naïve vaccinees were also at a greater risk for COVID-19-related-hospitalization compared to those who were previously infected.

Individuals who were previously infected with SARS-CoV-2 seem to gain additional protection from a subsequent single-dose vaccine regimen. Though this finding corresponds to previous reports^{24,25}, we could not demonstrate significance in our cohort.

The advantageous protection afforded by natural immunity that this analysis demonstrates could be explained by the more extensive immune response to the SARS-CoV-2 proteins than that generated by the anti-spike protein immune activation conferred by the vaccine^{26,27}. However, as a correlate of protection is yet to be proven^{1,28}, including the role of B-Cell²⁹ and T-cell immunity^{30,31}, this remains a hypothesis.

Our study has several limitations. First, as the Delta variant was the dominant strain in Israel during the outcome period, the decreased long-term protection of the vaccine compared to that afforded by previous infection cannot be ascertained against other strains. Second, our analysis addressed protection afforded solely by the BioNTech/Pfizer mRNA BNT162b2 vaccine, and therefore does not address other vaccines or long-term protection following a third dose, of which the deployment is underway in Israel. Additionally, as this is an observational real-world study, where PCR screening was not performed by protocol, we might be underestimating asymptomatic infections, as these individuals often do not get tested.

Lastly, although we controlled for age, sex, and region of residence, our results might be affected by differences between the groups in terms of health behaviors (such as social distancing and mask wearing), a possible confounder that was not assessed. As individuals with chronic illness were primarily vaccinated between December and February, confounding by indication needs to be considered; however, adjusting for obesity, cardiovascular disease, diabetes, hypertension, chronic kidney disease, chronic obstructive pulmonary disease, cancer and immunosuppression had only a small impact on the estimate of effect as compared to the unadjusted OR. Therefore, residual confounding by unmeasured factors is unlikely.

This analysis demonstrated that natural immunity affords longer lasting and stronger protection against infection, symptomatic disease and hospitalization due to the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity. Notably, individuals who were previously infected with SARS-CoV-2 and given a single dose of the BNT162b2 vaccine gained additional protection against the Delta variant. The long-term protection provided by a third dose, recently administered in Israel, is still unknown.

References

1. Krammer F. A correlate of protection for SARS-CoV-2 vaccines is urgently needed. *Nat Med* 2021 277 [Internet] 2021 [cited 2021 Aug 9];27(7):1147–8. Available from: <https://www.nature.com/articles/s41591-021-01432-4>
2. Polack FP, Thomas SJ, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *N Engl J Med* [Internet] 2020 [cited 2021 Mar 10];383(27):2603–15. Available from: <http://www.nejm.org/doi/10.1056/NEJMoa2034577>
3. Dagan N, Barda N, Kepten E, et al. BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting. *N Engl J Med* [Internet] 2021 [cited 2021 Apr 20];384(15). Available from: <https://pubmed.ncbi.nlm.nih.gov/33626250/>
4. Chodick G, Tene L, Rotem RS, et al. The Effectiveness of the Two-Dose BNT162b2 Vaccine: Analysis of Real-World Data. *Clin Infect Dis* [Internet] 2021 [cited 2021 Jul 22];Available from: <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab438/6276888>
5. Seow J, Graham C, Merrick B, et al. Longitudinal observation and decline of neutralizing antibody responses in the three months following SARS-CoV-2 infection in humans. *Nat Microbiol* [Internet] 2020;5(12):1598–607. Available from: <https://doi.org/10.1038/s41564-020-00813-8>
6. Ruopp MD, Strymish J, Dryjowicz-Burek J, Creedon K, Gupta K. Durability of SARS-CoV-2 IgG Antibody Among Residents in a Long-Term Care Community. *J Am Med Dir Assoc* [Internet] 2021;22(3):510–1. Available from: <https://pubmed.ncbi.nlm.nih.gov/33515497>

7. Shrotri M, Navaratnam AMD, Nguyen V, et al. Spike-antibody waning after second dose of BNT162b2 or ChAdOx1. *Lancet* [Internet] 2021 [cited 2021 Jul 22];0(0). Available from:
<http://www.thelancet.com/article/S0140673621016421/fulltext>
8. Mizrahi B, Lotan R, Kalkstein N, et al. Correlation of SARS-CoV-2 Breakthrough Infections to Time-from-vaccine; Preliminary Study. *medRxiv* [Internet] 2021 [cited 2021 Aug 12];2021.07.29.21261317. Available from:
<https://www.medrxiv.org/content/10.1101/2021.07.29.21261317v1>
9. Hansen CH, Michlmayr D, Gubbels SM, Mølbak K, Ethelberg S. Assessment of protection against reinfection with SARS-CoV-2 among 4 million PCR-tested individuals in Denmark in 2020: a population-level observational study. *Lancet* [Internet] 2021 [cited 2021 Aug 12];397(10280):1204–12. Available from: <http://www.thelancet.com/article/S0140673621005754/fulltext>
10. Iwasaki A. What reinfections mean for COVID-19. *Lancet Infect Dis* 2021;21(1):3–5.
11. Tomassini S, Kotecha D, Bird PW, Folwell A, Biju S, Tang JW. Setting the criteria for SARS-CoV-2 reinfection—six possible cases. *J Infect* 2020;
12. C CD. Reinfection [Internet]. 2020;(March 4, 2020). Available from:
<https://www.cdc.gov/coronavirus/2019-ncov/php/reinfection.html>
13. Perez G, Banon T, Gazit S, et al. A 1 to 1000 SARS-CoV-2 reinfection proportion in members of a large healthcare provider in Israel: a preliminary report. *medRxiv* [Internet] 2021;2021.03.06.21253051. Available from:
<http://medrxiv.org/content/early/2021/03/08/2021.03.06.21253051.abstract>
14. Lumley SF, O'Donnell D, Stoesser NE, et al. Antibody Status and Incidence of SARS-CoV-2 Infection in Health Care Workers. *N Engl J Med* [Internet] 2021

- [cited 2021 Mar 15];384(6):533–40. Available from:
<http://www.nejm.org/doi/10.1056/NEJMoa2034545>
15. COVID-19 in Israel dashboard. 2021;
16. Decline in Vaccine Effectiveness Against Infection and Symptomatic Illness
[Internet]. [cited 2021 Jul 22]. Available from:
<https://www.gov.il/en/Departments/news/05072021-03>
17. Bernal JL, Andrews N, Gower C, et al. Effectiveness of Covid-19 Vaccines
against the B.1.617.2 (Delta) Variant. <https://doi.org/10.1056/NEJMoa2108891>
[Internet] 2021 [cited 2021 Jul 22];NEJMoa2108891. Available from:
<https://www.nejm.org/doi/full/10.1056/NEJMoa2108891>
18. Lustig Y, Zuckerman N, Nemet I, et al. Neutralising capacity against Delta
(B.1.617.2) and other variants of concern following Comirnaty (BNT162b2,
BioNTech/Pfizer) vaccination in health care workers, Israel. *Eurosurveillance*
[Internet] 2021 [cited 2021 Jul 22];26(26):2100557. Available from:
<https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.26.2100557>
19. Shalev V, Chodick G, Goren I, Silber H, Kokia E, Heymann AD. The use of an
automated patient registry to manage and monitor cardiovascular conditions
and related outcomes in a large health organization. *Int J Cardiol* [Internet]
2011 [cited 2021 Jul 5];152(3):345–9. Available from:
<https://pubmed.ncbi.nlm.nih.gov/20826019/>
20. D W, G C, V S, C G, E G. Prevalence and factors associated with resistant
hypertension in a large health maintenance organization in Israel. *Hypertens*
(Dallas, Tex 1979) [Internet] 2014 [cited 2021 Aug 16];64(3):501–7.
Available from: <https://pubmed.ncbi.nlm.nih.gov/24958503/>

21. Chodick G, Heymann AD, Shalev V, Kookia E. The epidemiology of diabetes in a large Israeli HMO. *Eur J Epidemiol* [Internet] 2003 [cited 2021 Jul 4];18(12):1143–6. Available from: <https://pubmed.ncbi.nlm.nih.gov/14758871/>
22. Coresh J, Turin TC, Matsushita K, et al. Decline in estimated glomerular filtration rate and subsequent risk of end-stage renal disease and mortality. *JAMA - J Am Med Assoc* [Internet] 2014 [cited 2021 Jul 4];311(24):2518–31. Available from: <https://pubmed.ncbi.nlm.nih.gov/24892770/>
23. Israel Center for Disease Control. Jerusalem I. Data from: Israel national cancer registry.
24. Cavanaugh AM. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021. *MMWR Morb Mortal Wkly Rep* [Internet] 2021 [cited 2021 Aug 13];70(32):1081–3. Available from: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm>
25. Stamatatos L, Czartoski J, Wan Y-H, et al. mRNA vaccination boosts cross-variant neutralizing antibodies elicited by SARS-CoV-2 infection. *Science* (80-) [Internet] 2021 [cited 2021 Aug 14];372(6549):1413–8. Available from: <https://science.sciencemag.org/content/372/6549/1413>
26. Bettini E, Locci M. SARS-CoV-2 mRNA Vaccines: Immunological Mechanism and Beyond. *Vaccines* [Internet] 2021 [cited 2021 Mar 15];9(2):147. Available from: [/pmc/articles/PMC7918810/](https://pmc/articles/PMC7918810/)
27. Sette A, Crotty S. Leading Edge Adaptive immunity to SARS-CoV-2 and COVID-19. *Cell* [Internet] 2021 [cited 2021 Aug 21];184:861–80. Available from: <https://doi.org/10.1016/j.cell.2021.01.007>
28. Chia WN, Zhu F, Ong SWX, et al. Dynamics of SARS-CoV-2 neutralising antibody responses and duration of immunity: a longitudinal study. *The Lancet*

Microbe [Internet] 2021 [cited 2021 Aug 14];2(6):e240–9. Available from:

<http://www.thelancet.com/article/S2666524721000252/fulltext>

29. Cho A, Muecksch F, Schaefer-Babajew D, et al. Antibody Evolution after SARS-CoV-2 mRNA Vaccination. bioRxiv [Internet] 2021 [cited 2021 Aug 21];2021.07.29.454333. Available from:
<https://www.biorxiv.org/content/10.1101/2021.07.29.454333v1>
30. Cohen KW, Linderman SL, Moodie Z, et al. Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells. Cell Reports Med 2021;2(7).
31. Lu Z, Laing ED, Pena-Damata J, et al. Durability of SARS-CoV-2-specific T cell responses at 12-months post-infection. bioRxiv [Internet] 2021 [cited 2021 Aug 21];2021.08.11.455984. Available from:
<https://www.biorxiv.org/content/10.1101/2021.08.11.455984v1>

Tables and figures

Table 1a. Characteristics of study population, model 1 and 2.

	Model 1 – with matching of time of first event		Model 2 – without matching of time of first event	
Characteristics	Previously infected (n=16,215)	Vaccinated individuals (n=16,215)	Previously infected (n=46,035)	Previously infected <i>and</i> vaccinated (n =46,035)
Age years, mean (SD)	36.1 (13.9)	36.1 (13.9)	36.1 (14.7)	36.1 (14.7)
Age group – no. (%)				
16 to 39 yr	9,889 (61.0)	9,889 (61.0)	28,157 (61.2)	28,157 (61.2)
40 to 59 yr	5,536 (34.1)	5,536 (34.1)	14,973 (32.5)	14,973 (32.5)
≥60 yr	790 (4.9)	790 (4.9)	2,905 (6.3)	2,905 (6.3)
Sex – no. (%)				
Female	7,428 (45.8)	7,428 (45.8)	22,661 (49.2)	22,661 (49.2)
Male	8,787 (54.2)	8,787 (54.2)	23,374 (50.8)	23,374 (50.8)
SES, mean (SD)	5.5 (1.9)	5.5 (1.9)	5.3 (1.9)	5.3 (1.9)
Comorbidities – no. (%)				
Hypertension	1,276 (7.9)	1,569 (9.7)	4,009 (8.7)	4,301 (9.3)
CVD	551 (3.4)	647 (4.0)	1,875 (4.1)	1830 (4.0)
DM	635 (3.9)	877 (5.4)	2207 (4.8)	2300 (5.0)
Immunocompromised	164 (1.0)	420 (2.6)	527 (1.1)	849 (1.8)
Obesity (BMI ≥30)	3,076 (19.0)	3,073 (19.0)	9,117 (19.8)	8,610 (18.7)
CKD	196 (1.2)	271 (1.7)	659 (1.4)	814 (1.8)
COPD	65 (0.4)	97 (0.6)	218 (0.5)	292 (0.6)
Cancer	324 (2.0)	636 (3.9)	1,044 (2.3)	1,364 (3.0)

SD – Standard Deviation; SES – Socioeconomic status on a scale from 1 (lowest) to 10; CVD –

Cardiovascular Diseases; DM – Diabetes Mellitus; CKD – Chronic Kidney Disease; COPD – Chronic

Obstructive Pulmonary Disease.

Table 1b. Characteristics of study population, model 3.

Characteristics	Previously infected (n=14,029)	Previously infected and single dose vaccinated (n=14,029)
Age years, mean (SD)	33.2 (14.0)	33.2 (14.0)
Age group – no. (%)		
16 to 39 yr	9543 (68.0)	9543 (68.0)
40 to 59 yr	3919 (27.9)	3919 (27.9)
≥60 yr	567 (4.0)	567 (4.0)
Sex – no. (%)		
Female	7467 (53.2)	7467 (53.2)
Male	6562 (46.8)	6562 (46.8)
SES, mean (SD)	4.7 (1.9)	4.7 (1.9)
Comorbidities		
Hypertension	892 (6.4)	1004 (7.2)
CVD	437 (3.1)	386 (2.8)
DM	529 (3.8)	600 (4.3)
Immunocompromised	127 (0.9)	145 (1.0)
Obesity (BMI ≥30)	2599 (18.5)	2772 (19.8)
CKD	137 (1.0)	162 (1.2)
COPD	30 (0.2)	53 (0.4)
Cancer	241 (1.7)	267 (1.9)

SD – Standard Deviation; SES – Socioeconomic status on a scale from 1 (lowest) to 10; CVD –

Cardiovascular Diseases; DM – Diabetes Mellitus; CKD – Chronic Kidney Disease; COPD – Chronic

Obstructive Pulmonary Disease.

Table 2a. OR for SARS-CoV-2 infection, model 1, previously infected vs. vaccinated

Variable	Category	β	OR	95%CI	P-value
Induced Immunity					
	Previously infected	Ref			
	Vaccinated	2.57	13.06	8.08 – 21.11	<0.001
SES		0.04	1.04	0.97 – 1.11	0.251
Age group, yr.					
	16-39	Ref			
	40-59	0.05	1.05	0.78 - 1.4	0.751
	≥ 60	0.99	2.7	1.68 – 4.34	<0.001
Sex					
	Female	Ref			
	Male	-0.03	0.97	0.76 – 1.25	0.841
Comorbidities					
	Obesity (BMI ≥ 30)	0.01	1.01	0.73 – 1.39	0.967
	Diabetes mellitus	-0.36	0.7	0.39 – 1.25	0.229
	Hypertension	0.1	1.11	0.72 – 1.72	0.641
	Cancer	0.37	1.44	0.85 – 2.44	0.171
	CKD	0.53	1.7	0.83 – 3.46	0.146
	COPD	-0.46	0.63	0.15 – 2.66	0.529
	Immunosuppression	-0.1	0.91	0.42 – 1.97	0.803
	Cardiovascular diseases	0.26	1.3	0.75 – 2.25	0.343

OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10; CVD –

Cardiovascular Diseases; CKD – Chronic Kidney Disease; COPD – Chronic Obstructive Pulmonary Disease.

Table 2b. OR for Symptomatic SARS-CoV-2 infection, model 1, previously infected
vs. vaccinated

Variable	Category	β	OR	95%CI	P-value
Induced Immunity					
	Previously infected	Ref			
	Vaccinated	3.3	27.02	12.7 – 57.5	<0.001
SES		0.04	1.04	0.96 – 1.12	0.312
Age group, yr.					
	16-39	Ref			
	40-59	0.19	1.21	0.88 – 1.67	0.25
	≥60	1.06	2.89	1.68 – 4.99	<0.001
Sex					
	Female	Ref			
	Male	-0.19	0.82	0.62 – 1.1	0.185
Comorbidities					
	Obesity (BMI≥30)	0.02	1.02	0.71 – 1.48	0.899
	Diabetes mellitus	-0.31	0.73	0.37 – 1.43	0.361
	Hypertension	0.12	1.13	0.69 – 1.85	0.623
	Cancer	0.37	1.45	0.8 – 2.62	0.217
	CKD	0.1	1.1	0.42 – 2.87	0.846
	COPD	-0.78	0.46	0.06 – 3.41	0.445
	Immunosuppression	-0.37	0.69	0.25 – 1.89	0.468
	Cardiovascular diseases	0.03	1.03	0.52 – 2.03	0.941

OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10; CVD –

Cardiovascular Diseases; CKD – Chronic Kidney Disease; COPD – Chronic Obstructive Pulmonary Disease.

Table 3a. OR for SARS-CoV-2 infection, model 2, previously infected vs. vaccinated

Variable	Category	β	OR	95%CI	P-value
Induced Immunity					
	Previously infected	Ref			
	Vaccinated	1.78	5.96	4.85 – 7.33	<0.001
SES		0.07	1.07	1.03 – 1.11	<0.001
Age group, yr.					
	16-39	Ref			
	40-59	0.06	1.06	0.9 – 1.26	0.481
	≥60	0.79	2.2	1.66 – 2.92	<0.001
Sex					
	Female	Ref			
	Male	-0.01	0.99	0.85 - 1.14	0.842
Comorbidities					
	Obesity (BMI≥30)	0.12	1.13	0.94 – 1.36	0.202
	Diabetes mellitus	-0.15	0.86	0.61 – 1.22	0.4
	Hypertension	-0.12	0.89	0.67 – 1.17	0.402
	Cancer	0.2	1.22	0.85 – 1.76	0.283
	CKD	0.3	1.35	0.85 – 2.14	0.207
	COPD	0.48	1.62	0.88 – 2.97	0.121
	Immunosuppression	-0.03	0.98	0.57 – 1.66	0.925
	Cardiovascular diseases	0.08	1.09	0.77 – 1.53	0.638

OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10; CVD –

Cardiovascular Diseases; CKD – Chronic Kidney Disease; COPD – Chronic Obstructive Pulmonary Disease.

Table 3b. OR for Symptomatic SARS-CoV-2 infection, model 2, previously infected vs. vaccinated

Variable	Category	β	OR	95%CI	P-value
Induced Immunity					
	Previously infected	Ref			
	Vaccinated	1.96	7.13	5.51 – 9.21	<0.001
SES		0.07	1.07	1.02 – 1.12	0.003
Age group, yr.					
	16-39	Ref			
	40-59	0.09	1.1	0.9 – 1.33	0.35
	≥60	0.8	2.23	1.61 – 3.09	<0.001
Sex					
	Female	Ref			
	Male	-0.02	0.98	0.82 – 1.16	0.785
Comorbidities					
	Obesity (BMI≥30)	0.16	1.18	0.95 – 1.46	0.133
	Diabetes mellitus	-0.11	0.89	0.61 – 1.32	0.571
	Hypertension	-0.01	0.99	0.72 – 1.35	0.943
	Cancer	0.08	1.09	0.7 – 1.69	0.71
	CKD	0.13	1.14	0.65 – 1.98	0.654
	COPD	0.5	1.65	0.82 – 3.31	0.162
	Immunosuppression	0	1	0.54 – 1.85	0.999
	Cardiovascular diseases	0	1	0.67 – 1.5	0.99

OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10; CVD –

Cardiovascular Diseases; CKD – Chronic Kidney Disease; COPD – Chronic Obstructive Pulmonary Disease.

Table 4a. OR for SARS-CoV-2 infection, model 3, previously infected vs. previously infected and single-dose-vaccinated

Variable	Category	β	OR	95%CI	P-value
Induced Immunity					
	Previously infected	Ref			
	Previously infected and vaccinated	-0.64	0.53	0.3 – 0.92	0.024
SES		0.11	1.12	0.98 – 1.28	0.096
Age group, yr.					
	16-59	Ref			
	≥ 60	-0.81	0.44	0.06 – 3.22	0.422
Comorbidities					
	Immunosuppression	0.72	2.06	0.28 – 15.01	0.475

SES – Socioeconomic status on a scale from 1 (lowest) to 10

Table 4b. OR for Symptomatic SARS-CoV-2 infection, model 2, previously infected
vs. previously infected and vaccinated

Variable	Category	β	OR	95%CI	P-value
Induced Immunity					
	Previously infected	Ref			
	Previously infected and vaccinated	-0.43	0.65	0.34 – 1.25	0.194
SES		0.06	1.06	0.9 – 1.24	0.508
Age group, yr.					
	16-59	Ref			
	≥ 60	-16.9	0	0.0 – inf	0.996
Comorbidities					
	Immunosuppression	1.15	3.14	0.43 – 23.01	0.26

OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10.

Table S1. OR for COVID-19-related hospitalizations, model 1, previously infected
vs. vaccinated

Variable	Category	β	OR hospitalized	95%CI	P-value
Induced Immunity					
	Previously infected	Ref			
	Vaccinated	2.09	8.06	1.01 – 64.55	0.049
SES		0.05	1.05	0.72 – 1.53	0.81
Age ≥ 60 yrs (16-39, ref)		5.08	160.9	19.91 – 1300.44	<0.001

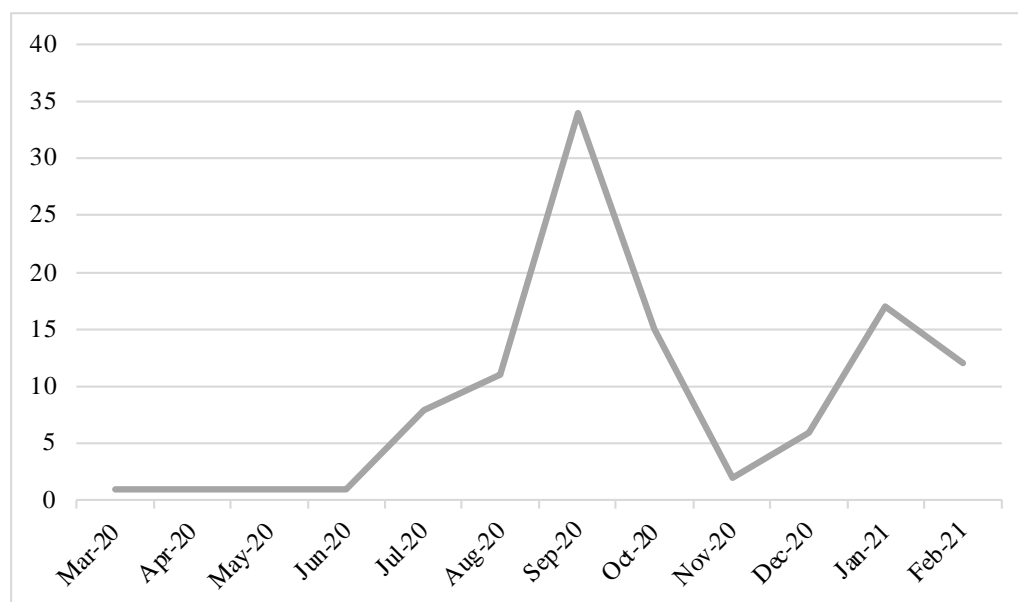
OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10

Table S2. OR for COVID-19-related hospitalizations, model 2, previously infected
vs. vaccinated

Variable	Category	β	OR hospitalized	95%CI	P-value
Induced Immunity					
	Previously infected	Ref			
	Vaccinated	1.95	7.03	2.1 – 23.59	0.002
SES		-0.07	0.93	0.74 – 1.17	0.547
Age ≥ 60 yrs (16-39, ref)		4.3	73.5	25.09 – 215.29	<0.001

OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10

Figure 1. Time of first infection in those reinfected between June and August 2021, model 2.



Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021

Alyson M. Cavanaugh, DPT, PhD^{1,2}; Kevin B. Spicer, MD, PhD^{2,3}; Douglas Thoroughman, PhD^{2,4}; Connor Glick, MS²; Kathleen Winter, PhD^{2,5}

On August 6, 2021, this report was posted as an MMWR Early Release on the MMWR website (<https://www.cdc.gov/mmwr>).

Although laboratory evidence suggests that antibody responses following COVID-19 vaccination provide better neutralization of some circulating variants than does natural infection (1,2), few real-world epidemiologic studies exist to support the benefit of vaccination for previously infected persons. This report details the findings of a case-control evaluation of the association between vaccination and SARS-CoV-2 reinfection in Kentucky during May–June 2021 among persons previously infected with SARS-CoV-2 in 2020. Kentucky residents who were not vaccinated had 2.34 times the odds of reinfection compared with those who were fully vaccinated (odds ratio [OR] = 2.34; 95% confidence interval [CI] = 1.58–3.47). These findings suggest that among persons with previous SARS-CoV-2 infection, full vaccination provides additional protection against reinfection. To reduce their risk of infection, all eligible persons should be offered vaccination, even if they have been previously infected with SARS-CoV-2.*

Kentucky residents aged ≥18 years with SARS-CoV-2 infection confirmed by positive nucleic acid amplification test (NAAT) or antigen test results[†] reported in Kentucky's National Electronic Disease Surveillance System (NEDSS) during March–December 2020 were eligible for inclusion. NEDSS data for all Kentucky COVID-19 cases were imported into a REDCap database that contains laboratory test results and case investigation data, including dates of death for deceased patients reported to public health authorities (3). The REDCap database was queried to identify previously infected persons, excluding COVID-19 cases resulting in death before May 1, 2021. A case-patient was defined as a Kentucky resident with laboratory-confirmed SARS-CoV-2 infection in 2020 and a subsequent positive NAAT or antigen test result during May 1–June 30, 2021. May and June were selected because of vaccine supply and eligibility requirement considerations; this period was more likely to reflect resident choice to be

vaccinated, rather than eligibility to receive vaccine.[§] Control participants were Kentucky residents with laboratory-confirmed SARS-CoV-2 infection in 2020 who were not reinfected through June 30, 2021. Case-patients and controls were matched on a 1:2 ratio based on sex, age (within 3 years), and date of initial positive SARS-CoV-2 test (within 1 week). Date of initial positive test result refers to the specimen collection date, if available. The report date in NEDSS was used if specimen collection date was missing. Random matching was performed to select controls when multiple possible controls were available to match per case (4).

Vaccination status was determined using data from the Kentucky Immunization Registry (KYIR). Case-patients and controls were matched to the KYIR database using first name, last name, and date of birth. Case-patients were considered fully vaccinated if a single dose of Janssen (Johnson & Johnson) or a second dose of an mRNA vaccine (Pfizer-BioNTech or Moderna) was received ≥14 days before the reinfection date. For controls, the same definition was applied, using the reinfection date of the matched case-patient. Partial vaccination was defined as receipt of ≥1 dose of vaccine, but either the vaccination series was not completed or the final dose was received <14 days before the case-patient's reinfection date. Using conditional logistic regression, ORs and CIs were used to compare no vaccination and partial vaccination with full vaccination among case-patients and controls. SAS (version 9.4; SAS Institute) was used for matching and statistical analyses. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[¶]

Overall, 246 case-patients met eligibility requirements and were successfully matched by age, sex, and date of initial infection with 492 controls. Among the population included in the analysis, 60.6% were female, and 204 (82.9%) case-patients were initially infected during October–December 2020

* https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2F%2Finfo-by-product%2Fclinical-considerations.html#CoV-19-vaccination

[†] <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>

[§] May and June were selected for two primary reasons. First, when vaccination supplies were low, some previously infected persons were deferring vaccination for 90 days to allow never-infected persons priority for available vaccine; however, by May 2021, deferral for 90 days was no longer a reason for those infected in 2020 to remain unvaccinated. Second, although vaccination eligibility was initially restricted based on age, comorbidities, and occupation, by April 5, 2021, all Kentucky residents aged ≥16 years became eligible for vaccination (<https://chfs.ky.gov/agencies/dph/covid19/Cv19VaccineFAskedQ.pdf>). Thus, vaccination status in May or June 2021 might more accurately reflect choice rather than eligibility to be vaccinated.

[¶] 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

Summary**What is already known about this topic?**

Reinfection with human coronaviruses, including SARS-CoV-2, the virus that causes COVID-19, has been documented. Currently, limited evidence concerning the protection afforded by vaccination against reinfection with SARS-CoV-2 is available.

What is added by this report?

Among Kentucky residents infected with SARS-CoV-2 in 2020, vaccination status of those reinfected during May–June 2021 was compared with that of residents who were not reinfected. In this case-control study, being unvaccinated was associated with 2.34 times the odds of reinfection compared with being fully vaccinated.

What are the implications for public health practice?

To reduce their likelihood for future infection, all eligible persons should be offered COVID-19 vaccine, even those with previous SARS-CoV-2 infection.

(Table 1). Among case-patients, 20.3% were fully vaccinated compared with 34.3% of controls (Table 2). Kentucky residents with previous infections who were unvaccinated had 2.34 times the odds of reinfection (OR = 2.34; 95% CI = 1.58–3.47) compared with those who were fully vaccinated; partial vaccination was not significantly associated with reinfection (OR = 1.56; 95% CI = 0.81–3.01).

Discussion

This study found that among Kentucky residents who were previously infected with SARS-CoV-2 in 2020, those who were unvaccinated against COVID-19 had significantly higher likelihood of reinfection during May and June 2021. This finding supports the CDC recommendation that all eligible persons be offered COVID-19 vaccination, regardless of previous SARS-CoV-2 infection status.

Reinfection with SARS-CoV-2 has been documented, but the scientific understanding of natural infection-derived immunity is still emerging (5). The duration of immunity resulting from natural infection, although not well understood, is suspected to persist for ≥ 90 days in most persons.** The emergence of new variants might affect the duration of infection-acquired immunity, and laboratory studies have shown that sera from previously infected persons might offer weak or inconsistent responses against several variants of concern (2,6). For example, a recent laboratory study found that sera collected from previously infected persons before they were vaccinated provided a relatively weaker, and in some cases absent, neutralization response to the B.1.351 (Beta) variant when compared with the original Wuhan-Hu-1 strain (1). Sera from the same persons after vaccination showed a heightened

neutralization response to the Beta variant, suggesting that vaccination enhances the immune response even to a variant to which the infected person had not been previously exposed. Although such laboratory evidence continues to suggest that vaccination provides improved neutralization of SARS-CoV-2 variants, limited evidence in real-world settings to date corroborates the findings that vaccination can provide improved protection for previously infected persons. The findings from this study suggest that among previously infected persons, full vaccination is associated with reduced likelihood of reinfection, and, conversely, being unvaccinated is associated with higher likelihood of being reinfected.

The lack of a significant association with partial versus full vaccination should be interpreted with caution given the small numbers of partially vaccinated persons included in the analysis (6.9% of case-patients and 7.9% of controls), which limited statistical power. The lower odds of reinfection among the partially vaccinated group compared with the unvaccinated group is suggestive of a protective effect and consistent with findings from previous studies indicating higher titers after the first mRNA vaccine dose in persons who were previously infected (7,8).

The findings in this report are subject to at least five limitations. First, reinfection was not confirmed through whole genome sequencing, which would be necessary to definitively prove that the reinfection was caused from a distinct virus relative to the first infection. Although in some cases the repeat positive test could be indicative of prolonged viral shedding or failure to clear the initial viral infection (9), given the time between initial and subsequent positive molecular tests among participants in this study, reinfection is the most likely explanation. Second, persons who have been vaccinated are possibly less likely to get tested. Therefore, the association of reinfection and lack of vaccination might be overestimated. Third, vaccine doses administered at federal or out-of-state sites are not typically entered in KYIR, so vaccination data are possibly missing for some persons in these analyses. In addition, inconsistencies in name and date of birth between KYIR and NEDSS might limit ability to match the two databases. Because case investigations include questions regarding vaccination, and KYIR might be updated during the case investigation process, vaccination data might be more likely to be missing for controls. Thus, the OR might be even more favorable for vaccination. Fourth, although case-patients and controls were matched based on age, sex, and date of initial infection, other unknown confounders might be present. Finally, this is a retrospective study design using data from a single state during a 2-month period; therefore, these findings cannot be used to infer causation. Additional prospective studies with larger populations are warranted to support these findings.

** <https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>

TABLE 1. Demographic characteristics of COVID-19 patients with reinfection (case-patients) and COVID-19 patients who were not reinfected (control participants) — Kentucky, May–June 2021

Characteristic	No. (%)	
	Case-patients* (n = 246)	Control participants† (n = 492)
Age group, yrs		
18–29	46 (18.7)	89 (18.1)
30–39	37 (15.0)	83 (16.9)
40–49	43 (17.5)	80 (16.3)
50–59	44 (17.9)	88 (17.9)
60–69	27 (11.0)	51 (10.4)
70–79	28 (11.4)	58 (11.8)
≥80	21 (8.5)	43 (8.7)
Sex		
Female	149 (60.6)	298 (60.6)
Month of initial infection in 2020		
March	0 (0)	3 (0.6)
April	7 (2.8)	11 (2.2)
May	2 (0.8)	2 (0.4)
June	4 (1.6)	11 (2.2)
July	8 (3.3)	17 (3.5)
August	8 (3.3)	13 (2.6)
September	13 (5.3)	22 (4.5)
October	36 (14.6)	78 (15.9)
November	72 (29.3)	141 (28.7)
December	96 (39.0)	194 (39.4)

* Case-patients were eligible for inclusion if initial infection occurred during March–December 2020, and a subsequent positive nucleic acid amplification or antigen test result was received during May–June 2021 (using date of specimen collection). Cases for analyses were restricted to persons aged ≥18 years at time of reinfection.

† Controls were matched by sex, age (within 3 years), and time of initial infection diagnosis (within 7 days).

These findings suggest that among persons with previous SARS-CoV-2 infection, full vaccination provides additional protection against reinfection. Among previously infected Kentucky residents, those who were not vaccinated were more than twice as likely to be reinfected compared with those with full vaccination. All eligible persons should be offered vaccination, including those with previous SARS-CoV-2 infection, to reduce their risk for future infection.

Acknowledgments

Kentucky's local health departments, disease investigators, and regional epidemiologists; Kentucky Department for Public Health immunization and data team members; Suzanne Beavers, CDC.

Corresponding author: Alyson M. Cavanaugh, qds1@cdc.gov.

¹Epidemic Intelligence Service, CDC; ²Kentucky Department for Public Health; ³Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, CDC; ⁴Division of State and Local Readiness, Center for Preparedness and Response, CDC; ⁵College of Public Health, University of Kentucky, Lexington, Kentucky.

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

TABLE 2. Association of SARS-CoV-2 reinfection* with COVID-19 vaccination status — Kentucky, May–June 2021

Vaccination status	No. (%)		OR (95% CI) [†]
	Case-patients	Control participants	
Not vaccinated	179 (72.8)	284 (57.7)	2.34 (1.58–3.47)
Partially vaccinated [¶]	17 (6.9)	39 (7.9)	1.56 (0.81–3.01)
Fully vaccinated [§]	50 (20.3)	169 (34.3)	Ref
Total	246 (100)	492 (100)	—

Abbreviations: CI = confidence interval; NAAT = nucleic acid amplification test; OR = odds ratio; Ref = referent group.

* All case-patients (reinfected) and control participants (not reinfected) had previous SARS-CoV-2 infection documented by positive NAAT or antigen test results during March–December 2020. Reinfection was defined as receipt of positive NAAT or antigen test results during May 1–June 30, 2021.

[†] Estimated based on conditional logistic regression.

[§] Case-patients were considered partially vaccinated if ≥1 dose of vaccine was received, but the vaccination series was either not completed or the final dose was received <14 days before their reinfection date. For control participants, the same criteria were applied, using the matched case-patient's reinfection date.

[¶] Case-patients and control participants were considered fully vaccinated if a complete COVID-19 vaccine series was received ≥14 days before the case-patient's reinfection date.

References

1. Stamatatos L, Czartoski J, Wan YH, et al. mRNA vaccination boosts cross-variant neutralizing antibodies elicited by SARS-CoV-2 infection. *Science* 2021. Epub March 27, 2021. PMID:33766944 <https://doi.org/10.1126/science.abg9175>
2. Deng X, Garcia-Knight MA, Khalid MM, et al. Transmission, infectivity, and neutralization of a spike L452R SARS-CoV-2 variant. *medRxiv* [Preprint posted online March 9, 2021] <https://www.medrxiv.org/content/10.1101/2021.03.07.21252647v1>
3. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81. PMID:18929686 <https://doi.org/10.1016/j.jbi.2008.08.010>
4. Mounib EL, Satchi T. Automating the selection of controls in case-control studies. Cary, NC: SAS Institute; 2000. <https://support.sas.com/resources/papers/proceedings/proceedings/sugi25/25/po/25p230.pdf>
5. Sui Y, Bekele Y, Berzofsky JA. Potential SARS-CoV-2 immune correlates of protection in infection and vaccine immunization. *Pathogens* 2021;10:138. PMID:33573221 <https://doi.org/10.3390/pathogens10020138>
6. Wang P, Nair MS, Liu L, et al. Increased resistance of SARS-CoV-2 variants B.1.351 and B.1.1.7 to antibody neutralization. *bioRxiv* [Preprint posted online February 4, 2021]. <https://www.biorxiv.org/content/10.1101/2021.01.25.428137v2>
7. Saadat S, Rikhtegaran Tehrani Z, Logue J, et al. Binding and neutralization antibody titers after a single vaccine dose in health care workers previously infected with SARS-CoV-2. *JAMA* 2021;325:1467–9. PMID:33646292 <https://doi.org/10.1001/jama.2021.3341>
8. Manisty C, Otter AD, Treibel TA, et al. Antibody response to first BNT162b2 dose in previously SARS-CoV-2-infected individuals. *Lancet* 2021;397:1057–8. PMID:33640038 [https://doi.org/10.1016/S0140-6736\(21\)00501-8](https://doi.org/10.1016/S0140-6736(21)00501-8)
9. Cevik M, Tate M, Lloyd O, Maraolo AE, Schafers J, Ho A. SARS-CoV-2, SARS-CoV, and MERS-CoV viral load dynamics, duration of viral shedding, and infectiousness: a systematic review and meta-analysis. *Lancet Microbe* 2021;2:e13–22. PMID:33521734 [https://doi.org/10.1016/S2666-5247\(20\)30172-5](https://doi.org/10.1016/S2666-5247(20)30172-5)



Exhibit N



COVID-19

Reinfection with COVID-19

Updated Aug. 6, 2021 [Print](#)

Cases of reinfection with COVID-19 have been reported, but remain rare.

In general, reinfection means a person was infected (got sick) once, recovered, and then later became infected again. Based on what we know from similar viruses, some reinfections are expected. We are still learning more about COVID-19. Ongoing COVID-19 studies will help us understand:

- How likely is reinfection
- How often reinfection occurs
- How soon after the first infection can reinfection take place
- How severe are cases of reinfection
- Who might be at higher risk for reinfection
- What reinfection means for a person's immunity
- If a person is able to spread COVID-19 to other people when reinfected

Delta Variant

The Delta variant causes more infections and spreads faster than earlier forms of the virus that causes COVID-19. It might cause more severe illness than previous strains in unvaccinated people.

- Vaccines continue to reduce a person's risk of contracting the virus that cause COVID-19, including this variant.
- Vaccines continue to be highly effective at preventing hospitalization and death, including against this variant.
- Fully vaccinated people with breakthrough infections from this variant appear to be infectious for a shorter period.
- Get vaccinated and wear masks indoors in public spaces to reduce the spread of this variant.

About the Delta Variant

Variants in the US

What CDC is doing

CDC is actively working to learn more about reinfection to inform public health action. CDC developed recommendations for public health professionals to help decide when and how to test someone for suspected reinfection. CDC has also provided information for state and local health departments to help investigate suspected cases of reinfection. We will update this guidance as we learn more about reinfection.

Important Ways to Slow the Spread of COVID-19

- Get a [COVID-19 vaccine](#) as soon as you can. [Find a vaccine.](#)
- Wear [a mask that covers your nose and mouth](#) to help protect yourself and others.
- [Stay 6 feet apart from others](#) who don't live with you.
- Avoid crowds and poorly ventilated indoor spaces.
- [Wash your hands often](#) with soap and water. Use hand sanitizer if soap and water aren't available.

More Information

[How to Protect Yourself & Others](#)

[How Do I Find a COVID-19 Vaccine?](#)

[About Variants of the Virus that Causes COVID-19 | CDC](#)

[Choosing Safer Activities | CDC](#)

Last Updated Aug. 6, 2021

COVID-19 Vaccine Breakthrough Case Investigation and Reporting



This page provides information and resources to help **public health departments** and **laboratories** investigate and report COVID-19 vaccine breakthrough cases.

- [Vaccine breakthrough cases](#) are expected. COVID-19 vaccines are effective and are a critical tool to bring the pandemic under control; however, no vaccine is 100% effective at preventing illness. Some fully vaccinated people will get sick, and some will even be hospitalized or die from COVID-19. However, there is evidence that vaccination may make illness less severe for those who are vaccinated and still get sick. The risk of infection, hospitalization, and death are all much lower in vaccinated people compared to unvaccinated.
- [More than 181 million](#) people in the United States have been fully vaccinated as of September 20, 2021. CDC is monitoring these cases among vaccinated persons and evaluating trends in order to better understand who is at risk for severe COVID-19 following vaccine breakthrough infection. Vaccinated people have also experienced asymptomatic infections.
- Current data suggest that COVID-19 vaccines authorized for use in the United States offer protection against most SARS-CoV-2 [variants](#) circulating in the United States.

What CDC is doing

CDC is leading multiple vaccine effectiveness studies and monitoring vaccine breakthroughs from a network of states to understand how COVID-19 vaccines are working and to identify patterns or trends in:

- Patients' characteristics, such as age or underlying medical conditions
- The specific vaccine that patients received
- Which SARS-CoV-2 variants are causing the infection

Defining a vaccine breakthrough infection

For the purpose of this surveillance, a vaccine breakthrough infection is defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person ≥ 14 days after they have completed all recommended doses of a U.S. Food and Drug Administration (FDA)-authorized COVID-19 vaccine.

Identifying and investigating hospitalized or fatal vaccine breakthrough cases

CDC monitors reported hospitalized or fatal vaccine breakthrough cases for clustering by patient demographics, geographic location, time since vaccination, vaccine type, and SARS-CoV-2 lineage. Reported data include hospitalized or fatal vaccine breakthrough cases due to any cause, including causes not related to COVID-19.

To the fullest extent possible, respiratory specimens that test positive for SARS-CoV-2 RNA are collected for genomic sequencing to identify the virus lineage that caused the infection.

Developing a data access and management system for reporting COVID-19 vaccine breakthrough cases

CDC developed a national COVID-19 vaccine breakthrough REDCap database where designated state health department investigators can enter, store, and manage data for cases in their jurisdiction. State health departments have full access to data for cases reported from their jurisdiction.

State health departments voluntarily report vaccine breakthrough cases to CDC. On May 1, 2021, after collecting data on thousands of vaccine breakthrough infections, CDC changed the focus of how it uses data from this reporting system. One of the strengths of this system is collecting data on severe cases of vaccine breakthrough COVID-19 since it is likely that most of these types of vaccine breakthrough cases seek medical care and are diagnosed and reported as a COVID-19 case. CDC relies on a variety of additional approaches to comprehensively monitor vaccine impact. Previous data on all vaccine breakthrough cases reported to CDC from January–April 2021 are [available](#).

These states are publicly reporting information on vaccine breakthrough cases:

+

Ultimately, CDC will use the [National Notifiable Diseases Surveillance System \(NNDSS\)](#) to identify vaccine breakthrough cases. Once CDC has confirmed that a state can report vaccination history data to NNDSS, CDC will identify vaccine breakthrough cases through that system. At that time, the state health departments can stop reporting cases directly into the REDCap database. After this change, CDC will upload the available data reported to NNDSS into the REDCap database for further review and confirmation by the state health department.

Hospitalized or fatal COVID-19 vaccine breakthrough cases reported to CDC as of September 20, 2021

As of September 20, 2021, [more than 181 million people](#) in the United States had been fully vaccinated against COVID-19.

During the same time, CDC received reports from 50 U.S. states and territories of 19,136 patients with COVID-19 vaccine breakthrough infection who were hospitalized or died.

	Deaths		Hospitalized, non-fatal*	
Total	N=4,493		N=14,643	
Females	1,977	(44%)	7,035	(48%)
People aged ≥65 years	3,882	(86%)	10,136	(69%)
Asymptomatic or not COVID-related**	839	(19%)	2,912	(20%)

*This table separates all reported vaccine breakthrough infections that resulted in hospitalization and/or death into two columns. While most deaths were also among hospitalized individuals, a small number were not.

**Includes cases in which the patient did not have symptoms of COVID-19, or their hospitalization or death was not COVID-related. For example, people may be hospitalized for reasons other than COVID-19, such as an auto accident, and test positive when screened upon hospital admission.

Previous data on all vaccine breakthrough cases reported to CDC from January–April 2021 are [available](#).

How to interpret these data

The number of COVID-19 vaccine breakthrough infections reported to CDC are an undercount of all SARS-CoV-2 infections among fully vaccinated persons, especially of asymptomatic or mild infections. National surveillance relies on passive and voluntary reporting, and data are not complete or representative. These surveillance data are a snapshot and help identify patterns and look for signals among vaccine breakthrough cases.

Information on patients with vaccine breakthrough infection who were hospitalized or died will continue to be updated. Studies are being conducted in multiple U.S. sites that will include information on all vaccine breakthrough infections regardless of clinical status to supplement the national surveillance

regardless of clinical status to supplement the national surveillance.

COVID-19 vaccines are effective

- To date, no unexpected patterns have been identified in the case demographics or vaccine characteristics among people with reported vaccine breakthrough infections.
- COVID-19 vaccines are effective. CDC recommends that everyone 12 years of age and older get a COVID-19 vaccine as soon as they can.
- A vaccine breakthrough infection happens when a fully vaccinated person gets infected with COVID-19. People with vaccine breakthrough infections may spread COVID-19 to others.
- Even if you are fully vaccinated, if you live in an area with [substantial or high transmission](#) of COVID-19, you will be better protected if you wear a mask when you are in indoor public places.
- Currently, CDC is recommending that moderately to severely immunocompromised people [receive an additional dose](#) of mRNA COVID-19 vaccine at least 28 days after a second dose of [Pfizer-BioNTech COVID-19 vaccine](#) or [Moderna COVID-19 vaccine](#).

For local health departments, healthcare providers, and clinical laboratories

+

- CDC encourages local health departments, healthcare providers, and clinical laboratories that identify a COVID-19 vaccine breakthrough case to:
 - Request the respiratory specimen be held for further testing.
 - Report the case to the state health department where the individual resides for further investigation and reporting to the national system.
- COVID-19 vaccine breakthrough cases that result in hospitalization or death should be reported to the [Vaccine Adverse Event Reporting System \(VAERS\)](#) [↗](#) .

For state health departments

+

- If a possible vaccine breakthrough case is identified:
 - Request that the clinical or public health laboratory hold any residual respiratory specimens from the positive SARS-CoV-2 test.
 - Report the available case data to NNDSS, per normal procedures.
 - Review CDC’s screening questions to assess whether the case meets the COVID-19 vaccine breakthrough investigation criteria.
- If the reported case meets those criteria, CDC encourages state health departments to:
 - Follow the steps for initiating a COVID-19 vaccine breakthrough case investigation.
 - Record the case in the COVID-19 vaccine breakthrough REDCap database.
- Because CDC would like to characterize the SARS-CoV-2 lineages responsible for COVID-19 vaccine breakthrough cases, including variants, CDC requests state health departments to:
 - Report sequence results from a state public health laboratory, commercial reference laboratory, or academic laboratory by entering the PANGO lineage and GenBank or GISAID accession number into the COVID-19 vaccine breakthrough REDCap database.
 - If SARS-CoV-2 sequencing will not be performed locally and an acceptable clinical respiratory specimen is available, provide instructions for the testing laboratory to send the residual respiratory specimen to CDC.
 - For cases with a known RT-PCR cycle threshold (Ct) value, submit only specimens with Ct value ≤28 to CDC for sequencing. (Sequencing is not feasible with higher Ct values.)
 - If the Ct value is not known (e.g., positive by antigen test only or by a molecular test that does not provide a Ct value), submit the positive specimen may still be submitted to CDC for RT-PCR and possible sequencing.

How to send CDC sequence data or respiratory specimens from suspected vaccine breakthrough cases:

+

- CDC would like to receive sequence data and respiratory specimens from COVID-19 vaccine breakthrough cases to assess the SARS-CoV-2 lineage, including variants. When a vaccine breakthrough case is identified, the health department will contact the laboratory to request that any residual respiratory specimen from the positive test be held for sequencing at CDC.

- The health department also will request the specimen ID numbers and the Ct value for positive RT-PCR results.
- If SARS-CoV-2 sequencing will not be performed locally and a specimen is available, the state public health laboratory should request the residual clinical respiratory specimen for subsequent shipping to CDC.
 - For cases with a known RT-PCR cycle threshold (Ct) value, submit only specimens with Ct value ≤ 28 to CDC for sequencing.
 - If the Ct value is not known (e.g., positive by antigen test only or by a molecular test that does not provide a Ct value), the positive specimen may still be submitted to CDC for RT-PCR and potential sequencing.
- If your laboratory identifies a COVID-19 vaccine breakthrough case, please report it to your state health department so it can initiate the investigation with CDC.
- These instructions can also be found here: NS3 Submission Guidance [Documents](#) [↗](#) .

Resources to support submitting breakthrough case data to CDC

[COVID-19 vaccine breakthrough case investigation form](#)  [2 pages]

[Public health investigations of COVID-19 vaccine breakthrough cases protocol](#)  [10 pages]

For more information on COVID-19 breakthrough cases:

- [What You Should Know About the Possibility of COVID-19 Illness After Vaccination](#)
- [COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021](#)

Page last reviewed: September 24, 2021

Most of the World's Vaccines Likely Won't Prevent Infection From Omicron

They do seem to offer significant protection against severe illness, but the consequences of rapidly spreading infection worry many public health experts.



By Stephanie Nolen

Published Dec. 19, 2021 Updated Dec. 21, 2021

A growing body of preliminary research suggests the Covid vaccines used in most of the world offer almost no defense against becoming infected by the highly contagious Omicron variant.

All vaccines still seem to provide a significant degree of protection against serious illness from Omicron, which is the most crucial goal. But only the Pfizer and Moderna shots, when reinforced by a booster, appear to have initial success at stopping infections, and these vaccines are unavailable in most of the world.

The other shots — including those from AstraZeneca, Johnson & Johnson and vaccines manufactured in China and Russia — do little to nothing to stop the spread of Omicron, early research shows. And because most countries have built their inoculation programs around these vaccines, the gap could have a profound impact on the course of the pandemic.

A global surge of infections in a world where billions of people remain unvaccinated not only threatens the health of vulnerable individuals but also increases the opportunity for the emergence of yet more variants. The disparity in the ability of countries to weather the pandemic will almost certainly deepen. And the news about limited vaccine efficacy against Omicron infection could depress demand for vaccination throughout the developing world, where many people are already hesitant or preoccupied with other health problems.

Most evidence so far is based on laboratory experiments, which do not capture the full range of the body's immune response, and not from tracking the effect on real-world populations. The results are striking, however.

The Pfizer and Moderna shots use the new mRNA technology, which has consistently offered the best protection against infection with every variant. All of the other vaccines are based on older methods of triggering an immune response.

The Chinese vaccines Sinopharm and Sinovac — which make up almost half of all shots delivered globally — offer almost zero protection from Omicron infection. The great majority of people in China have received these shots, which are also widely used in low-and middle-income countries such as Mexico and Brazil.

A preliminary effectiveness study in Britain found that the Oxford-AstraZeneca vaccine showed no ability to stop Omicron infection six months after vaccination. Ninety percent of vaccinated people in India received this shot, under the brand name Covishield; it has also been widely used across much of sub-Saharan Africa, where Covax, the global Covid vaccine program, has distributed 67 million doses of it to 44 countries.

Workers unloaded a shipment of China's Sinopharm vaccine in Bujumbura, Burundi. China's Sinopharm and Sinovac vaccines together make up almost half of all the shots delivered globally. Tchandrou Nitanga/Agence France-Presse — Getty Images

Administering the AstraZeneca shot in Milan. Alessandro Grassani for The New York Times

Researchers predict that Russia's Sputnik vaccine, which is also being used in Africa and Latin America, will show similarly dismal rates of protection against Omicron.

Demand for the Johnson & Johnson vaccine had been surging in Africa, because its single-shot delivery regimen makes it easy to deliver in low-resource settings. But it too has shown a negligible ability to block Omicron infection.

Antibodies are the first line of defense induced by vaccines. But the shots also stimulate the growth of T cells, and preliminary studies suggest that these T cells still recognize the Omicron variant, which is important in preventing severe disease.

“What you lose first is protection against asymptomatic mild infection, what you retain much better is protection against severe disease and death,” said John Moore, a virologist at Weill Cornell Medicine in New York. He called it “a silver lining” that Omicron so far appears less lethal than the Delta variant.

But this protection will not be enough to prevent Omicron from causing global disruption, said J. Stephen Morrison, director of the Global Health Policy Center at the Center for International and Strategic Studies.

“The sheer scale of infection will overwhelm health systems, simply because the denominator will be potentially so big,” he said. “If you have a burst of infection worldwide, a shock, what does the world look like on the other side of it? Is it, ‘The war is over,’ or, ‘The war has just entered another phase’? We haven’t begun thinking about any of that.”

Updated 3 hours ago

- Where vaccination rates are low in the U.S., the reasons vary.
- The N.B.A. cuts isolation time as dozens test positive.
- Goldman Sachs will mandate boosters and more coronavirus testing.

People with breakthrough cases may experience only asymptomatic infection or mild illness, but they can pass the virus to unvaccinated people, who could fall more severely ill, and become a source of new variants.

A Sinovac vaccination in Cachoeira do Piria, Brazil, in January. Experts fear news of limited vaccine efficacy against Omicron will depress demand for vaccination in places where people are already hesitant. Tarso Sarraf/Agence France-Presse — Getty Images

Monks signed up for AstraZeneca's shot in Bangkok in April. Adam Dean for The New York Times

Dr. Seth Berkley, the chief executive of Gavi, the global vaccine alliance, said that more data was needed before drawing conclusions about vaccines' effectiveness against Omicron — and that accelerated vaccination should continue to be the focus of pandemic response.

Preliminary data from South Africa suggest that with Omicron, there is a much higher chance of people who already had Covid getting reinfected than there was with the original virus and previous variants. But some public health experts say they believe that countries that have already been through brutal waves of Covid, such as Brazil and India, may have a buffer against Omicron, and vaccination after infection produces high antibody levels.

“The combination of vaccination and exposure to the virus seems to be stronger than only having the vaccine,” said Ramanan Laxminarayan, an epidemiologist. India, he noted, has an adult vaccination rate of only about 40 percent but 90 percent exposure to the virus in some areas.

“Without a doubt Omicron is going to flood through India,” he said. “But hopefully India is protected to some extent because of vaccination and exposure.”

China does not have this layer of protection to back up its weak vaccines. Because of China's aggressive efforts to stop spread of the virus within its borders, relatively few people have previous exposure. Only an estimated 7 percent of people in Wuhan, where the pandemic began, were infected.

The Coronavirus Pandemic: Key Things to Know

End-of-year gatherings. The new Covid surge is prompting worries and cancellations as we exit 2021. The Times asked experts to share some guidance on travel and gathering safely, as well as some tips on using at-home virus tests (if you can find them). Here is what to do if you test positive for the coronavirus.

Much of Latin America has relied on the Chinese and Russian vaccines, and on AstraZeneca. Mario Rosemblatt, a professor of immunology at the University of Chile, said that more than 90 percent of Chileans had had two doses of one vaccine, but the great majority of these were Coronavac, the Sinovac shot. High vaccination coverage combined with early reports that Omicron does not cause serious illness is leading to a false sense of security in the country, he said.

“We have to get people to understand that it doesn't work like that: If you get high transmissibility you're going to have the health system saturated because the number of people getting ill will be higher,” he said.

Brazil has recommended that all vaccinated people get a third dose, and it started using Pfizer's vaccine for all boosters, but only 40 percent of the vaccinated have turned up to get the extra shot. Dr. Amilcar Tanuri, a virologist at the Federal University of Rio de Janeiro, said with cautious optimism that the high levels of previous Covid exposure might blunt Omicron's impact but noted that the most vulnerable Brazilians, vaccinated first, got Coronavac, and tens of millions more were given AstraZeneca.

A woman given the Johnson & Johnson vaccine at a clinic in Chongwe District, Zambia. Demand for J.&J.'s single-shot regimen had been surging in Africa, as it is easy to deliver in low-resource settings. João Silva/The New York Times

Delivery of Covidshield vaccines, India's formulation of the AstraZeneca shot, to Gosaba Island in West Bengal, India. Rupak De Chowdhuri/Reuters

Mr. Morrison called Omicron's ability to evade the protection of vaccination "a massive setback" for low- and middle-income countries, where, far from any discussion of boosters, the focus is still on delivering first shots.

"The world gets cleaved into two parts, right?" he said. "It's those that have a quick path toward boosters versus those who have had very limited progress and suddenly they're subject to this new lashing."

Just 13 percent of people in Africa have received at least one dose of a Covid vaccine.

Dr. Laxminarayan said the Indian government, to which he is an occasional adviser, was considering booster shots, but the Delta variant still poses a significant threat in India, and two vaccine doses offer protection against Delta. That presents the government with a difficult choice between focusing on getting people who remain unvaccinated, or only partly vaccinated, to two doses, or trying to get boosters to older people and those with high-risk medical conditions as protection against Omicron.

The news that the non-mRNA vaccines offer little protection against infection from Omicron may further erode demand for shots in countries already struggling to build demand, Mr. Morrison said.

“This challenges the whole value of vaccines,” he said. “If you’re so far behind and then you suffer this, it’s going to feed anti-vaccine sentiment and weaken confidence.”

Tolbert Nyenswah, a senior researcher with the Johns Hopkins Bloomberg School of Public Health, said the emerging threat to countries in the global south that have relied on non-mRNA vaccines was an indictment of wealthy countries’ failure to share that technology or help build production points in low- and middle-income countries.

As a consequence, dangerous variants will continue to emerge from areas with low vaccination coverage and will prolong the pandemic, predicted Dr. Nyenswah, who was deputy minister of health in Liberia through that country’s worst Ebola outbreak.

Filling out paperwork to receive the Sputnik vaccine in Moscow in July. Sergey Ponomarev for The New York Times

Nurses went house-to-house to deliver the Sinopharm vaccine in the Villa Maria del Triunfo neighborhood of Lima, Peru. Martin Mejia/Associated Press

Dr. Berkley at Gavi said it would be a serious mistake for countries to ease up on their vaccination push or to assume that only mRNA vaccines are worth distributing.

“We may be seeing a situation where countries say, ‘If developed countries don’t want these vaccines, then we don’t want these vaccines,’” he said. “That, of course, would be the wrong interpretation, if it turns out that these vaccines prevent against severe disease and death.”

Lynsey Chutel, Carl Zimmer and Emily Schmall contributed reporting.

EXHIBIT Q

ATTACHMENT E

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION**

**JAMES RODDEN,
et al.**

Plaintiffs,

v.

**DR. ANTHONY FAUCI,
et al.**

Defendants.

CA 3:21-cv-00317

I, Dr. Anish Koka, declare as follows:

1. I am an adult of sound mind and make this statement voluntarily, based upon my own personal knowledge, education, and experience.

EXPERIENCE & CREDENTIALS

2. I am a practicing Cardiologist. I am board certified in Internal Medicine and the subspecialty of Cardiology. I am also board certified in the cardiac subspecialties of Echocardiography, and Nuclear Medicine.

3. My assessment of vaccine related myocarditis is based on numerous peer reviewed studies of mRNA vaccines that have been published.

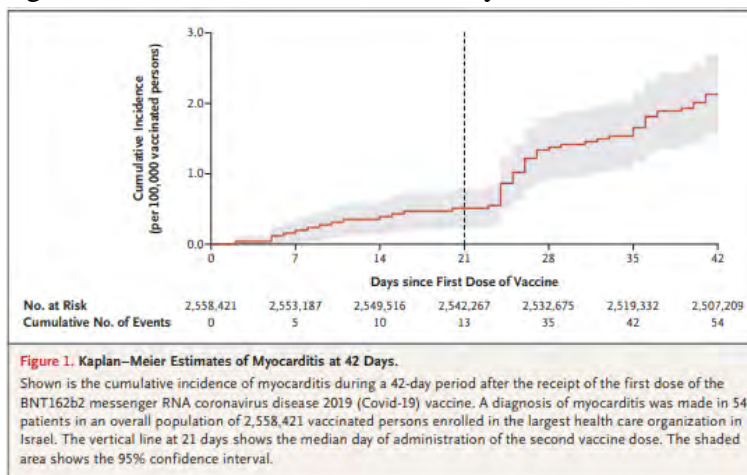
4. I have not and will not receive any financial or other compensation to prepare this Declaration.
5. I have no prior relationship with any of the plaintiffs.
6. I have been asked to provide my opinion the potential long term cardiac consequences of vaccines.

OPINIONS

7. There is little doubt that the mRNA vaccines are associated with myocarditis. This has been confirmed by multiple datasets, and the CDC agrees there is a ["likely association."](#)
8. The putative mechanisms are currently [being explored](#) by researchers.
9. Some of the datasets are summarized below:

Myocarditis after Covid-19 Vaccination in a Large Health Care Organization. N Engl J Med 2021;385:2132-9.

This was an evaluation of the incidence of myocarditis after the receipt of the BNT162b2 mRNA vaccine in a single health care organization in Israel that demonstrates a significant increase in incidence of myocarditis after the second dose of the vaccine.



The diagnosis of myocarditis occurred throughout the post-vaccination period, but there appeared to be an increase approximately 3 to 5 days after the second vaccine dose. Most cases were mild or moderate in severity, but one patient had cardiogenic shock, and one

patient with preexisting cardiac disease died of an unknown cause soon after hospital discharge.

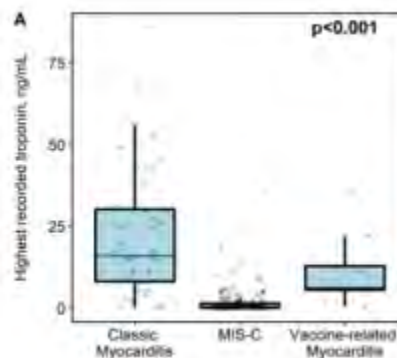
Montgomery J, Ryan M, Engler R, et al. Myocarditis following immunization with mRNA COVID-19 vaccines in members of the US military. JAMA Cardiol 2021 June 29 (Epub ahead of print).

This was a report from the US military noted an incidence of 8.2 cases of myocarditis per 100,000 male service members.

Barda N, Dagan N, Ben-Shlomo Y, et al. Safety of the BNT162b2 mRNA Covid-19 vaccine in a nationwide setting. N Engl J Med 2021;385:1078-1090.

10. An Israeli study demonstrated 2.7 excess cases of myocarditis per 100,000 vaccinated persons.

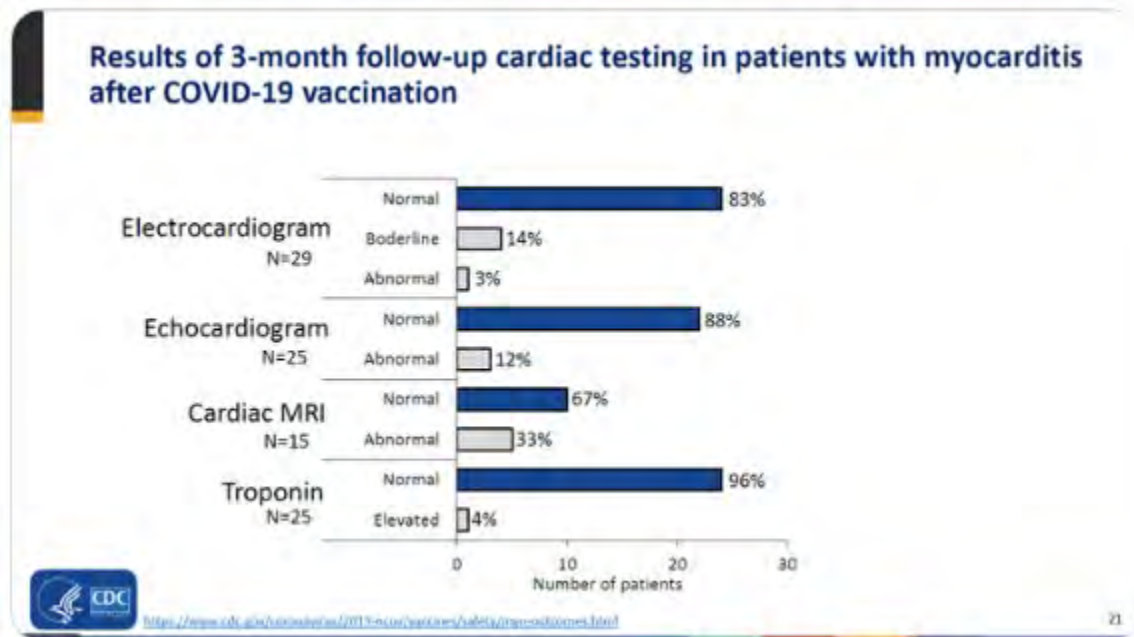
11. Vaccine related myocarditis is associated with a significant leak of cardiac enzymes from the heart and thus can result in permanent damage to the heart (as presented to the Vaccines and Related Biological Products Advisory Committee (VRBPAC))
(Comparison of MIS-C Related Myocarditis, Classic Viral Myocarditis, and COVID-19 Vaccine related Myocarditis in Children, Patel et. al.)



12. While vaccine myocarditis is associated with a reduction in function of the heart that appears to rapidly normalize, cardiac Magnetic Resonance imaging finds the formation of

scar after vaccine myocarditis is similar to findings in non-vaccine myocarditis. ([Hanneman et. al](https://pubs.rsna.org/doi/10.1148/ryct.210252)) (<https://pubs.rsna.org/doi/10.1148/ryct.210252>)

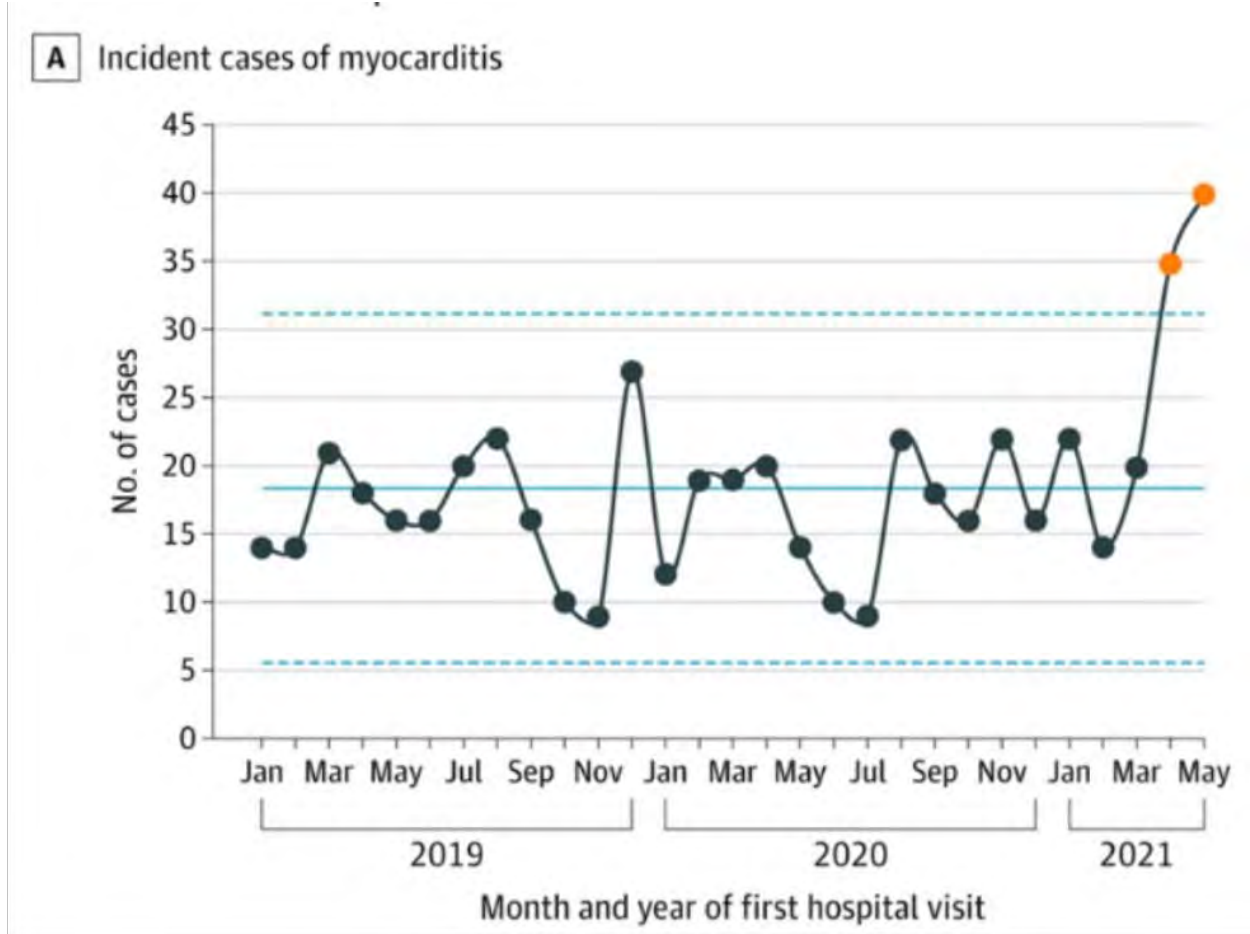
13. There is limited long-term follow up at present, but early evidence suggests about one-third of patients with vaccine myocarditis have evidence of scar/fibrosis seen in 3 month follow up.



14. The presence of scar, or fibrosis in the heart has potential long term consequences. A systemic review of the literature found that the presence of scar by cardiac MRI is associated with an increased risk of death, heart failure, the need for cardiac transplantation, and serious cardiac arrhythmias. (<https://www.ahajournals.org/doi/10.1161/CIRCIMAGING.120.011492>)

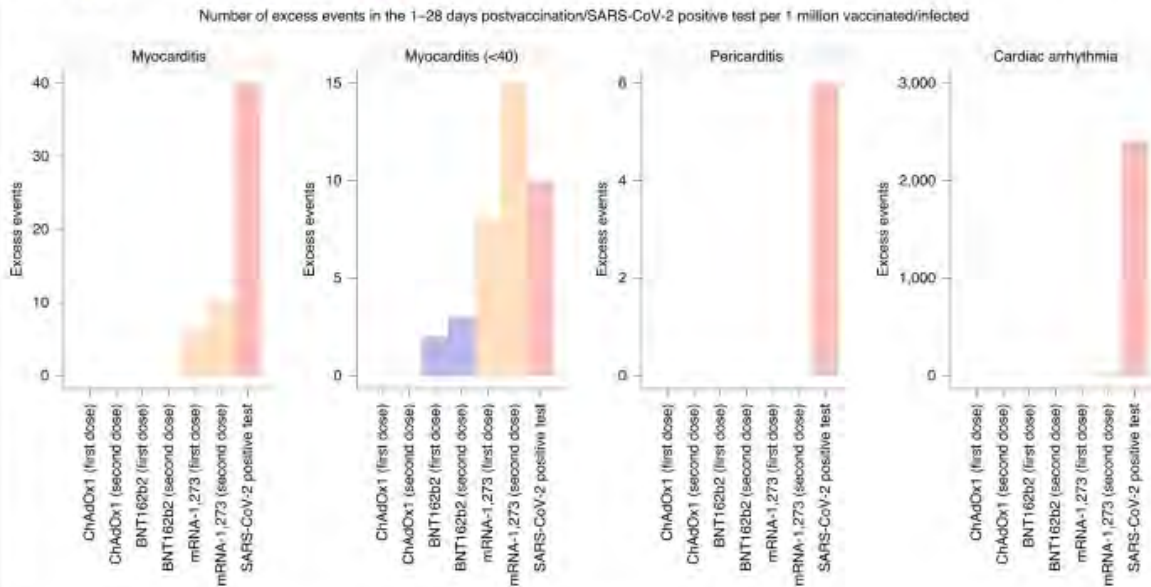
15. It has been suggested that the risk of myocarditis from contracting Sars-COV2 is higher than the risk of myocarditis from the mRNA vaccines. But, importantly, a study in the Journal of the American Medical Association (<https://jamanetwork.com/journals/jama/fullarticle/2782900>) that required a diagnosis of myocarditis to have supportive laboratory and imaging data showed

the diagnosis of myocarditis peaked only after widespread vaccine administration.



16. A recent nature study (<https://www.nature.com/articles/s41591-021-01630-0>) also suggests that the risk of myocarditis varies by type of vaccine, with the highest risk noted after the second dose of the Moderna vaccine. Importantly, rates of myocarditis related to a second dose of a Moderna vaccine are higher than rates of myocarditis related to SARS-COV2 infection.

Fig. 2: Number of excess events due to exposure per 1 million exposed, as reported in Supplementary Table 10.



When IRR did not show a significant increase of incidence over the 1–28 days postvaccination or a SARS-CoV-2 positive test, absolute measures are not given.

17. In summary, vaccine related myocarditis is a potentially serious medical condition that can lead to fibrosis in heart muscle. Fibrosis and scarring found within the heart muscle has been associated with long term complications related to cardiac arrhythmias and even sudden cardiac death. It is not yet known what the long-term sequelae will be for those patients who have developed scarring and fibrosis related to vaccine myocarditis. Rates of vaccine myocarditis in certain sub-populations may exceed the risks from SARS-Cov2 associated myocarditis.

18. I declare under penalty of perjury under the laws of the United States of America that, to the best of my knowledge, the foregoing is true and correct this 20th day of December, at Philadelphia, Pennsylvania.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'A. Koka', with a long horizontal line extending to the right.

Dr. Anish Koka, M.D.
Doctor of Internal Medicine and Cardiology

EXHIBIT R

aabadi@optonline.net

From: Aaron <aronhertz123@gmail.com>
Sent: Sunday, January 9, 2022 8:55 PM
To: undisclosed-recipients:
Subject: A massive list of Scientific Study's To Prove That The Covid 19 Vaccines Are Dangerous compiled by someone else

This merits its own email, and is too long to put with anything else anyway:

Over a Thousand Scientific Studies To Prove That The Covid 19 Vaccines Are Dangerous

Cerebral venous thrombosis after COVID-19 vaccination in the UK: a multicentre cohort study: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)01608-1/](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01608-1/)

Fatal cerebral hemorrhage after COVID-19 vaccine:

<https://pubmed.ncbi.nlm.nih.gov/33928772/>

Myocarditis after mRNA vaccination against SARS-CoV-2, a case

series: <https://www.sciencedirect.com/science/article/pii/S2666602221000409>

Three cases of acute venous thromboembolism in women after vaccination against COVID-19: <https://www.sciencedirect.com/science/article/pii/S2213333X21003929>

Acute thrombosis of the coronary tree after vaccination against COVID-

19: <https://www.sciencedirect.com/science/article/abs/pii/S1936879821003988>

US case reports of cerebral venous sinus thrombosis with thrombocytopenia after vaccination with Ad26.COV2.S (against covid-19), March 2 to April 21,

2020: <https://pubmed.ncbi.nlm.nih.gov/33929487/>

Portal vein thrombosis associated with ChAdOx1 nCov-19

vaccine: [https://www.thelancet.com/journals/langas/article/PIIS2468-1253\(21\)00197-7/](https://www.thelancet.com/journals/langas/article/PIIS2468-1253(21)00197-7/)

Management of cerebral and splanchnic vein thrombosis associated with thrombocytopenia in subjects previously vaccinated with Vaxzevria (AstraZeneca): position statement of the

Italian Society for the Study of Hemostasis and Thrombosis

(SISET): <https://pubmed.ncbi.nlm.nih.gov/33871350/>

Vaccine-induced immune immune thrombotic thrombocytopenia and cerebral venous sinus thrombosis after vaccination with COVID-19; a systematic

review: <https://www.sciencedirect.com/science/article/pii/S0022510X21003014>

Thrombosis with thrombocytopenia syndrome associated with COVID-19

vaccines: <https://www.sciencedirect.com/science/article/abs/pii/S0735675721004381>

Covid-19 vaccine-induced thrombosis and thrombocytopenia: a commentary on an important and practical clinical

dilemma: <https://www.sciencedirect.com/science/article/abs/pii/S0033062021000505>

Thrombosis with thrombocytopenia syndrome associated with COVID-19 viral vector

vaccines: <https://www.sciencedirect.com/science/article/abs/pii/S0953620521001904>

COVID-19 vaccine-induced immune-immune thrombotic thrombocytopenia: an emerging cause of splanchnic vein

thrombosis: <https://www.sciencedirect.com/science/article/pii/S1665268121000557>

The roles of platelets in COVID-19-associated coagulopathy and vaccine-induced immune thrombotic immune thrombocytopenia

(covid): <https://www.sciencedirect.com/science/article/pii/S1050173821000967>

Roots of autoimmunity of thrombotic events after COVID-19

vaccination: <https://www.sciencedirect.com/science/article/abs/pii/S1568997221002160>

Cerebral venous sinus thrombosis after vaccination: the United Kingdom

experience: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)01788-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01788-8/fulltext)

Thrombotic immune thrombocytopenia induced by SARS-CoV-2

vaccine: <https://www.nejm.org/doi/full/10.1056/nejme2106315>

Myocarditis after immunization with COVID-19 mRNA vaccines in members of the US military. This article reports that in “23 male patients, including 22 previously healthy military members, myocarditis was identified within 4 days after receipt of the vaccine”:

<https://jamanetwork.com/journals/jamacardiology/fullarticle/2781601>

Thrombosis and thrombocytopenia after vaccination with ChAdOx1 nCoV-

19: https://www.nejm.org/doi/full/10.1056/NEJMoa2104882?query=recirc_curatedRelated_article

Association of myocarditis with the BNT162b2 messenger RNA COVID-19 vaccine in a case series of children: <https://pubmed.ncbi.nlm.nih.gov/34374740/>

Thrombotic thrombocytopenia after vaccination with ChAdOx1 nCov-

19: https://www.nejm.org/doi/full/10.1056/NEJMoa2104840?query=recirc_curatedRelated_article

Post-mortem findings in vaccine-induced thrombotic thrombocytopenia (covid-19): <https://haematologica.org/article/view/haematol.2021.279075>

Thrombocytopenia, including immune thrombocytopenia after receiving COVID-19 mRNA vaccines reported to the Vaccine Adverse Event Reporting System (VAERS): <https://www.sciencedirect.com/science/article/pii/S0264410X21005247>

Acute symptomatic myocarditis in seven adolescents after Pfizer-BioNTech COVID-19 vaccination: <https://pediatrics.aappublications.org/content/early/2021/06/04/peds.2021-052478>

Aphasia seven days after the second dose of an mRNA-based SARS-CoV-2 vaccine. Brain MRI revealed an intracerebral hemorrhage (ICBH) in the left temporal lobe in a 52-year-old man. <https://www.sciencedirect.com/science/article/pii/S2589238X21000292#f0005>

Comparison of vaccine-induced thrombotic episodes between ChAdOx1 nCoV-19 and Ad26.COV.2.S vaccines: <https://www.sciencedirect.com/science/article/abs/pii/S0896841121000895>

Hypothesis behind the very rare cases of thrombosis with thrombocytopenia syndrome after SARS-CoV-2 vaccination: <https://www.sciencedirect.com/science/article/abs/pii/S0049384821003315>

Blood clots and bleeding episodes after BNT162b2 and ChAdOx1 nCoV-19 vaccination: analysis of European data: <https://www.sciencedirect.com/science/article/pii/S0896841121000937>

Cerebral venous thrombosis after BNT162b2 mRNA SARS-CoV-2 vaccine: <https://www.sciencedirect.com/science/article/abs/pii/S1052305721003098>

Primary adrenal insufficiency associated with thrombotic immune thrombocytopenia induced by the Oxford-AstraZeneca ChAdOx1 nCoV-19 vaccine

(VITT): <https://www.sciencedirect.com/science/article/pii/S0953620521002363>

Myocarditis and pericarditis after vaccination with COVID-19 mRNA: practical considerations for care

providers: <https://www.sciencedirect.com/science/article/pii/S0828282X21006243>

“Portal vein thrombosis occurring after the first dose of SARS-CoV-2 mRNA vaccine in a patient with antiphospholipid

syndrome”: <https://www.sciencedirect.com/science/article/pii/S2666572721000389>

Early results of bivalirudin treatment for thrombotic thrombocytopenia and cerebral venous sinus thrombosis after vaccination with

Ad26.COV2.S: <https://www.sciencedirect.com/science/article/pii/S0196064421003425>

Myocarditis, pericarditis and cardiomyopathy after COVID-19

vaccination: <https://www.sciencedirect.com/science/article/pii/S1443950621011562>

Mechanisms of immunothrombosis in vaccine-induced thrombotic thrombocytopenia (VITT) compared to natural SARS-CoV-2

infection: <https://www.sciencedirect.com/science/article/abs/pii/S0896841121000706>

Prothrombotic immune thrombocytopenia after COVID-19

vaccination: <https://www.sciencedirect.com/science/article/pii/S0006497121009411>

Vaccine-induced thrombotic thrombocytopenia: the dark chapter of a success

story: <https://www.sciencedirect.com/science/article/pii/S2589936821000256>

Cerebral venous sinus thrombosis negative for anti-PF4 antibody without thrombocytopenia after immunization with COVID-19 vaccine in a non-comorbid elderly Indian male treated with conventional heparin-warfarin based

anticoagulation: <https://www.sciencedirect.com/science/article/pii/S1871402121002046>

Thrombosis after COVID-19 vaccination: possible link to ACE

pathways: <https://www.sciencedirect.com/science/article/pii/S0049384821004369>

Cerebral venous sinus thrombosis in the U.S. population after SARS-CoV-2 vaccination with adenovirus and after COVID-

19: <https://www.sciencedirect.com/science/article/pii/S0735109721051949>

A rare case of a middle-aged Asian male with cerebral venous thrombosis after AstraZeneca COVID-19

vaccination: <https://www.sciencedirect.com/science/article/pii/S0735675721005714>

Cerebral venous sinus thrombosis and thrombocytopenia after COVID-19 vaccination: report of two cases in the United

Kingdom: <https://www.sciencedirect.com/science/article/abs/pii/S088915912100163X>

Immune thrombocytopenic purpura after vaccination with COVID-19 vaccine (ChAdOx1 nCov-19): <https://www.sciencedirect.com/science/article/abs/pii/S0006497121013963>.

Antiphospholipid antibodies and risk of thrombophilia after COVID-19 vaccination: the straw that breaks the camel's

back?: <https://docs.google.com/document/d/1XzajasO8VMMnC3CdxSBKks1o7kiOLXFQ>

Vaccine-induced thrombotic thrombocytopenia, a rare but severe case of friendly fire in the battle against the COVID-19 pandemic: What

pathogenesis?: <https://www.sciencedirect.com/science/article/pii/S0953620521002314>

Diagnostic-therapeutic recommendations of the ad-hoc FACME expert working group on the management of cerebral venous thrombosis related to COVID-19

vaccination: <https://www.sciencedirect.com/science/article/pii/S0213485321000839>

Thrombocytopenia and intracranial venous sinus thrombosis after exposure to the “AstraZeneca COVID-19 vaccine”: <https://pubmed.ncbi.nlm.nih.gov/33918932/>

Thrombocytopenia following Pfizer and Moderna SARS-CoV-2

vaccination: <https://pubmed.ncbi.nlm.nih.gov/33606296/>

Severe and refractory immune thrombocytopenia occurring after SARS-CoV-2

vaccination: <https://pubmed.ncbi.nlm.nih.gov/33854395/>

Purpuric rash and thrombocytopenia after mRNA-1273 (Modern) COVID-19

vaccine: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7996471/>

COVID-19 vaccination: information on the occurrence of arterial and venous thrombosis using data from Vigibase: <https://pubmed.ncbi.nlm.nih.gov/33863748/>

Cerebral venous thrombosis associated with the covid-19 vaccine in

Germany: <https://onlinelibrary.wiley.com/doi/10.1002/ana.26172>

Cerebral venous thrombosis following BNT162b2 mRNA vaccination of BNT162b2 against SARS-CoV-2: a black swan event: <https://pubmed.ncbi.nlm.nih.gov/34133027/>

The importance of recognizing cerebral venous thrombosis following anti-COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34001390/>

Thrombosis with thrombocytopenia after messenger RNA vaccine - 1273: <https://pubmed.ncbi.nlm.nih.gov/34181446/>

Blood clots and bleeding after BNT162b2 and ChAdOx1 nCoV-19 vaccination: an analysis of European data: <https://pubmed.ncbi.nlm.nih.gov/34174723/>

First dose of ChAdOx1 and BNT162b2 COVID-19 vaccines and thrombocytopenic, thromboembolic, and hemorrhagic events in Scotland: <https://www.nature.com/articles/s41591-021-01408-4>

Exacerbation of immune thrombocytopenia after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34075578/>

First report of a de novo iTTP episode associated with a COVID-19 mRNA-based anti-COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34105244/>

PF4 immunoassays in vaccine-induced thrombotic thrombocytopenia: <https://www.nejm.org/doi/full/10.1056/NEJMc2106383>

Antibody epitopes in vaccine-induced immune thrombotic thrombocytopenia: <https://www.nature.com/articles/s41586-021-03744-4>

Myocarditis with COVID-19 mRNA vaccines: <https://www.ahajournals.org/doi/pdf/10.1161/CIRCULATIONAHA.121.056135>

Myocarditis and pericarditis after COVID-19 vaccination: <https://jamanetwork.com/journals/jama/fullarticle/2782900>

Myocarditis temporally associated with COVID-19 vaccination: <https://www.ahajournals.org/doi/pdf/10.1161/CIRCULATIONAHA.121.055891>.

COVID-19 Vaccination Associated with Myocarditis in Adolescents: <https://pediatrics.aappublications.org/content/pediatrics/early/2021/08/12/peds.2021-053427.full.pdf>

Acute myocarditis after administration of BNT162b2 vaccine against COVID-19: <https://pubmed.ncbi.nlm.nih.gov/33994339/>

Temporal association between COVID-19 vaccine Ad26.COV2.S and acute myocarditis: case report and review of the literature: <https://www.sciencedirect.com/science/article/pii/S1553838921005789>

COVID-19 vaccine-induced myocarditis: a case report with review of the literature: <https://www.sciencedirect.com/science/article/pii/S1871402121002253>

Potential association between COVID-19 vaccine and myocarditis: clinical and CMR findings: <https://www.sciencedirect.com/science/article/pii/S1936878X2100485X>

Recurrence of acute myocarditis temporally associated with receipt of coronavirus mRNA disease vaccine 2019 (COVID-19) in a male adolescent: <https://www.sciencedirect.com/science/article/pii/S002234762100617X>

Fulminant myocarditis and systemic hyper inflammation temporally associated with BNT162b2 COVID-19 mRNA vaccination in two patients: <https://www.sciencedirect.com/science/article/pii/S0167527321012286>.

Acute myocarditis after administration of BNT162b2 vaccine: <https://www.sciencedirect.com/science/article/pii/S2214250921001530>

Lymphohistocytic myocarditis after vaccination with COVID-19 Ad26.COV2.S viral vector: <https://www.sciencedirect.com/science/article/pii/S2352906721001573>

Myocarditis following vaccination with BNT162b2 in a healthy male: <https://www.sciencedirect.com/science/article/pii/S0735675721005362>

Acute myocarditis after Comirnaty (Pfizer) vaccination in a healthy male with previous SARS-CoV-2 infection: <https://www.sciencedirect.com/science/article/pii/S1930043321005549>

Myopericarditis after Pfizer mRNA COVID-19 vaccination in adolescents: <https://www.sciencedirect.com/science/article/pii/S002234762100665X>

Pericarditis after administration of BNT162b2 mRNA COVID-19 mRNA vaccine: <https://www.sciencedirect.com/science/article/pii/S1885585721002218>

Acute myocarditis after vaccination with SARS-CoV-2 mRNA-1273

mRNA: <https://www.sciencedirect.com/science/article/pii/S2589790X21001931>

Temporal relationship between the second dose of BNT162b2 mRNA Covid-19 vaccine and cardiac involvement in a patient with previous SARS-COV-2

infection: <https://www.sciencedirect.com/science/article/pii/S2352906721000622>

Myopericarditis after vaccination with COVID-19 mRNA in adolescents 12 to 18 years of age: <https://www.sciencedirect.com/science/article/pii/S0022347621007368>

Acute myocarditis after SARS-CoV-2 vaccination in a 24-year-old

man: <https://www.sciencedirect.com/science/article/pii/S0870255121003243>

Important information on myopericarditis after vaccination with Pfizer COVID-19 mRNA in adolescents: <https://www.sciencedirect.com/science/article/pii/S0022347621007496>

A series of patients with myocarditis after vaccination against SARS-CoV-2 with mRNA-1279 and

BNT162b2: <https://www.sciencedirect.com/science/article/pii/S1936878X21004861>

Takotsubo cardiomyopathy after vaccination with mRNA COVID-

19: <https://www.sciencedirect.com/science/article/pii/S1443950621011331>

COVID-19 mRNA vaccination and

myocarditis: <https://pubmed.ncbi.nlm.nih.gov/34268277/>

COVID-19 vaccine and myocarditis: <https://pubmed.ncbi.nlm.nih.gov/34399967/>

Epidemiology and clinical features of myocarditis/pericarditis before the introduction of COVID-19 mRNA vaccine in Korean children: a multicenter

study <https://search.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/resource/en/covidwho-1360706>.

COVID-19 vaccines and myocarditis: <https://pubmed.ncbi.nlm.nih.gov/34246566/>

Myocarditis and other cardiovascular complications of COVID-19 mRNA-based COVID-19 vaccines [https://www.cureus.com/articles/61030-myocarditis-and-other-cardiovascular-](https://www.cureus.com/articles/61030-myocarditis-and-other-cardiovascular-complications-of-the-mrna-based-covid-19-vaccines)

[comp](https://www.cureus.com/articles/61030-myocarditis-and-other-cardiovascular-complications-of-the-mrna-based-covid-19-vaccines)lications-of-the-mrna-based-covid-19-

vaccines [https://www.cureus.com/articles/61030-myocarditis-and-other-cardiovascular-](https://www.cureus.com/articles/61030-myocarditis-and-other-cardiovascular-complications-of-the-mrna-based-covid-19-vaccines)
[complications-of-the-mrna-based-covid-19-vaccines](https://www.cureus.com/articles/61030-myocarditis-and-other-cardiovascular-complications-of-the-mrna-based-covid-19-vaccines)

Myocarditis, pericarditis, and cardiomyopathy after COVID-19

vaccination: <https://pubmed.ncbi.nlm.nih.gov/34340927/>

Myocarditis with covid-19 mRNA

vaccines: <https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.056135>

Association of myocarditis with COVID-19 mRNA vaccine in

children: <https://media.jamanetwork.com/news-item/association-of-myocarditis-with-mrna-co-vid-19-vaccine-in-children/>

Association of myocarditis with COVID-19 messenger RNA vaccine BNT162b2 in a case

series of children: <https://jamanetwork.com/journals/jamacardiology/fullarticle/2783052>

Myocarditis after immunization with COVID-19 mRNA vaccines in members of the U.S.

military: <https://jamanetwork.com/journals/jamacardiology/fullarticle/2781601%5C>

Myocarditis occurring after immunization with COVID-19 mRNA-based COVID-19

vaccines: <https://jamanetwork.com/journals/jamacardiology/fullarticle/2781600>

Myocarditis following immunization with Covid-19

mRNA: <https://www.nejm.org/doi/full/10.1056/NEJMc2109975>

Patients with acute myocarditis after vaccination with COVID-19

mRNA: <https://jamanetwork.com/journals/jamacardiology/fullarticle/2781602>

Myocarditis associated with vaccination with COVID-19

mRNA: <https://pubs.rsna.org/doi/10.1148/radiol.2021211430>

Symptomatic Acute Myocarditis in 7 Adolescents after Pfizer-BioNTech COVID-19

Vaccination: <https://pediatrics.aappublications.org/content/148/3/e2021052478>

Cardiovascular magnetic resonance imaging findings in young adult patients with acute myocarditis after COVID-19 mRNA vaccination: a case series: [https://jcmr-](https://jcmr-online.biomedcentral.com/articles/10.1186/s12968-021-00795-4)

[online.biomedcentral.com/articles/10.1186/s12968-021-00795-4](https://jcmr-online.biomedcentral.com/articles/10.1186/s12968-021-00795-4)

Clinical Guidance for Young People with Myocarditis and Pericarditis after Vaccination

with COVID-19 mRNA: <https://www.cps.ca/en/documents/position/clinical-guidance-for-youth-with-myocarditis-and-pericarditis>

Cardiac imaging of acute myocarditis after vaccination with COVID-19

mRNA: <https://pubmed.ncbi.nlm.nih.gov/34402228/>

Case report: acute myocarditis after second dose of mRNA-1273 SARS-CoV-2 mRNA vaccine: <https://academic.oup.com/ehjcr/article/5/8/ytab319/6339567>

Myocarditis / pericarditis associated with COVID-19 vaccine: https://science.gc.ca/eic/site/063.nsf/eng/h_98291.html

Transient cardiac injury in adolescents receiving the BNT162b2 mRNA COVID-19 vaccine: https://journals.lww.com/pidj/Abstract/9000/Transient_Cardiac_Injury_in_Adolescents_Receiving.95800.aspx

Perimyocarditis in adolescents after Pfizer-BioNTech COVID-19 vaccine: <https://academic.oup.com/jpids/advance-article/doi/10.1093/jpids/piab060/6329543>

The new COVID-19 mRNA vaccine platform and myocarditis: clues to the possible underlying mechanism: <https://pubmed.ncbi.nlm.nih.gov/34312010/>

Acute myocardial injury after COVID-19 vaccination: a case report and review of current evidence from the Vaccine Adverse Event Reporting System database: <https://pubmed.ncbi.nlm.nih.gov/34219532/>

Be alert to the risk of adverse cardiovascular events after COVID-19 vaccination: <https://www.xiahepublishing.com/m/2472-0712/ERHM-2021-00033>

Myocarditis associated with COVID-19 vaccination: echocardiographic, cardiac tomography, and magnetic resonance imaging findings: <https://www.ahajournals.org/doi/10.1161/CIRCIMAGING.121.013236>

In-depth evaluation of a case of presumed myocarditis after the second dose of COVID-19 mRNA vaccine: <https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.056038>

Occurrence of acute infarct-like myocarditis after COVID-19 vaccination: just an accidental coincidence or rather a vaccination-associated autoimmune myocarditis?: <https://pubmed.ncbi.nlm.nih.gov/34333695/>

Recurrence of acute myocarditis temporally associated with receipt of coronavirus mRNA disease vaccine 2019 (COVID-19) in a male adolescent: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8216855/>

Myocarditis after SARS-CoV-2 vaccination: a vaccine-induced reaction?: <https://pubmed.ncbi.nlm.nih.gov/34118375/>

Self-limited myocarditis presenting with chest pain and ST-segment elevation in adolescents after vaccination with the BNT162b2 mRNA

vaccine: <https://pubmed.ncbi.nlm.nih.gov/34180390/>

Myopericarditis in a previously healthy adolescent male after COVID-19 vaccination: Case report: <https://pubmed.ncbi.nlm.nih.gov/34133825/>

Biopsy-proven lymphocytic myocarditis after first COVID-19 mRNA vaccination in a 40-year-old man: case report: <https://pubmed.ncbi.nlm.nih.gov/34487236/>

Insights from a murine model of COVID-19 mRNA vaccine-induced myopericarditis: could accidental intravenous injection of a vaccine induce myopericarditis <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab741/6359059>

Unusual presentation of acute perimyocarditis after modern SARS-CoV-2 mRNA-1237 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34447639/>

Perimyocarditis after the first dose of mRNA-1273 SARS-CoV-2 (Modern) mRNA-1273 vaccine in a young healthy male: case report: <https://bmccardiovascdisord.biomedcentral.com/articles/10.1186/s12872-021-02183>

Acute myocarditis after the second dose of SARS-CoV-2 vaccine: serendipity or causal relationship: <https://pubmed.ncbi.nlm.nih.gov/34236331/>

Rhabdomyolysis and fasciitis induced by the COVID-19 mRNA vaccine: <https://pubmed.ncbi.nlm.nih.gov/34435250/>

COVID-19 vaccine-induced rhabdomyolysis: case report with literature review: <https://pubmed.ncbi.nlm.nih.gov/34186348/>.

GM1 ganglioside antibody and COVID-19-related Guillain Barre syndrome: case report, systemic review, and implications for vaccine development: <https://www.sciencedirect.com/science/article/pii/S2666354621000065>

Guillain-Barré syndrome after AstraZeneca COVID-19 vaccination: causal or casual association: <https://www.sciencedirect.com/science/article/pii/S0303846721004169>

Sensory Guillain-Barré syndrome after ChAdOx1 nCov-19 vaccine: report of two cases and review of the literature: <https://www.sciencedirect.com/science/article/pii/S0165572821002186>

Guillain-Barré syndrome after the first dose of SARS-CoV-2 vaccine: a temporary occurrence, not a causal association: <https://www.sciencedirect.com/science/article/pii/S2214250921000998>.

Guillain-Barré syndrome presenting as facial diplegia after vaccination with COVID-19: a case report: <https://www.sciencedirect.com/science/article/pii/S0736467921006442>

Guillain-Barré syndrome after the first injection of ChAdOx1 nCoV-19 vaccine: first report: <https://www.sciencedirect.com/science/article/pii/S0035378721005853>.

SARS-CoV-2 vaccines are not safe for those with Guillain-Barre syndrome following vaccination: <https://www.sciencedirect.com/science/article/pii/S2049080121005343>

Acute hyperactive encephalopathy following COVID-19 vaccination with dramatic response to methylprednisolone: a case report: <https://www.sciencedirect.com/science/article/pii/S2049080121007536>

Facial nerve palsy following administration of COVID-19 mRNA vaccines: analysis of self-report database: <https://www.sciencedirect.com/science/article/pii/S1201971221007049>

Neurological symptoms and neuroimaging alterations related to COVID-19 vaccine: cause or coincidence: <https://www.sciencedirect.com/science/article/pii/S0899707121003557>.

New-onset refractory status epilepticus after ChAdOx1 nCoV-19 vaccination: <https://www.sciencedirect.com/science/article/pii/S0165572821001569>

Acute myelitis and ChAdOx1 nCoV-19 vaccine: coincidental or causal association: <https://www.sciencedirect.com/science/article/pii/S0165572821002137>

Bell's palsy and SARS-CoV-2 vaccines: an unfolding story: <https://www.sciencedirect.com/science/article/pii/S1473309921002735>

Bell's palsy after the second dose of the Pfizer COVID-19 vaccine in a patient with a history of recurrent Bell's palsy: <https://www.sciencedirect.com/science/article/pii/S266635462100020X>

Acute-onset central serous retinopathy after immunization with COVID-19 mRNA vaccine.: <https://www.sciencedirect.com/science/article/pii/S2451993621001456>.

Bell's palsy after COVID-19 vaccination: case report: <https://www.sciencedirect.com/science/article/pii/S217358082100122X>.

An academic hospital experience assessing the risk of COVID-19 mRNA vaccine using patient's allergy

history: <https://www.sciencedirect.com/science/article/pii/S2213219821007972>

COVID-19 vaccine-induced axillary and pectoral lymphadenopathy in

PET: <https://www.sciencedirect.com/science/article/pii/S1930043321002612>

ANCA-associated vasculitis after Pfizer-BioNTech COVID-19

vaccine: <https://www.sciencedirect.com/science/article/pii/S0272638621007423>

Late cutaneous reactions after administration of COVID-19 mRNA

vaccines: <https://www.sciencedirect.com/science/article/pii/S2213219821007996>

COVID-19 vaccine-induced rhabdomyolysis: case report with review of the

literature: <https://www.sciencedirect.com/science/article/pii/S1871402121001880>

Clinical and pathologic correlates of skin reactions to COVID-19 vaccine, including V-REPP: a registry-based

study: <https://www.sciencedirect.com/science/article/pii/S0190962221024427>

Thrombosis with thrombocytopenia syndrome associated with COVID-19

vaccines: <https://www.sciencedirect.com/science/article/abs/pii/S0735675721004381>.

COVID-19 vaccine-associated anaphylaxis: a statement from the Anaphylaxis Committee of the World Allergy

Organization: <https://www.sciencedirect.com/science/article/pii/S1939455121000119>.

Cerebral venous sinus thrombosis negative for anti-PF4 antibody without thrombocytopenia after immunization with COVID-19 vaccine in an elderly, non-comorbid Indian male treated with conventional heparin-warfarin-based

anticoagulation: <https://www.sciencedirect.com/science/article/pii/S1871402121002046>.

Acute myocarditis after administration of BNT162b2 vaccine against COVID-

19: <https://www.sciencedirect.com/science/article/abs/pii/S188558572100133X>

Blood clots and bleeding after BNT162b2 and ChAdOx1 nCoV-19 vaccine: an analysis of European data: <https://www.sciencedirect.com/science/article/pii/S0896841121000937>.

immune thrombocytopenia associated with Pfizer-BioNTech's COVID-19 BNT162b2

mRNA vaccine: <https://www.sciencedirect.com/science/article/pii/S2214250921002018>.

Bullous drug eruption after the second dose of COVID-19 mRNA-1273 (Moderna) vaccine:
Case report: <https://www.sciencedirect.com/science/article/pii/S1876034121001878>.

COVID-19 RNA-based vaccines and the risk of prion disease:
[https://scivisionpub.com/pdfs/covid19rna-based-vaccines-and-the-risk-of-prion-dis](https://scivisionpub.com/pdfs/covid19rna-based-vaccines-and-the-risk-of-prion-disease-1503.pdf) ease-1503.pdf

This study notes that 115 pregnant women lost their babies, out of 827 who participated in a study on the safety of covid-19 vaccines: <https://www.nejm.org/doi/full/10.1056/NEJMoa2104983>.

Process-related impurities in the ChAdOx1 nCov-19 vaccine: <https://www.researchsquare.com/article/rs-477964/v1>

COVID-19 mRNA vaccine causing CNS inflammation: a case series: <https://link.springer.com/article/10.1007/s00415-021-10780-7>

Allergic reactions, including anaphylaxis, after receiving the first dose of the Pfizer-BioNTech COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33475702/>

Allergic reactions to the first COVID-19 vaccine: a potential role of polyethylene glycol: <https://pubmed.ncbi.nlm.nih.gov/33320974/>

Pfizer Vaccine Raises Allergy Concerns: <https://pubmed.ncbi.nlm.nih.gov/33384356/>

Allergic reactions, including anaphylaxis, after receiving the first dose of Pfizer-BioNTech COVID-19 vaccine – United States, December 14-23, 2020: <https://pubmed.ncbi.nlm.nih.gov/33444297/>

Allergic reactions, including anaphylaxis, after receiving first dose of Modern COVID-19 vaccine – United States, December 21, 2020-January 10, 2021: <https://pubmed.ncbi.nlm.nih.gov/33507892/>

Reports of anaphylaxis after coronavirus disease vaccination 2019, South Korea, February 26-April 30, 2021: <https://pubmed.ncbi.nlm.nih.gov/34414880/>

Reports of anaphylaxis after receiving COVID-19 mRNA vaccines in the U.S.-Dec 14, 2020-Jan 18, 2021: <https://pubmed.ncbi.nlm.nih.gov/33576785/>

Immunization practices and risk of anaphylaxis: a current, comprehensive update of COVID-19 vaccination data: <https://pubmed.ncbi.nlm.nih.gov/34269740/>

Relationship between pre-existing allergies and anaphylactic reactions following administration of COVID-19 mRNA vaccine: <https://pubmed.ncbi.nlm.nih.gov/34215453/>

Anaphylaxis Associated with COVID-19 mRNA Vaccines: Approach to Allergy Research: <https://pubmed.ncbi.nlm.nih.gov/33932618/>

Severe Allergic Reactions after COVID-19 Vaccination with the Pfizer / BioNTech Vaccine in Great Britain and the USA: Position Statement of the German Allergy Societies: German Medical Association of Allergologists (AeDA), German Society for Allergology and Clinical Immunology (DGAKI) and Society for Pediatric Allergology and Environmental Medicine (GPA): <https://pubmed.ncbi.nlm.nih.gov/33643776/>

Allergic reactions and anaphylaxis to LNP-based COVID-19 vaccines: <https://pubmed.ncbi.nlm.nih.gov/33571463/>

Reported orofacial adverse effects from COVID-19 vaccines: the known and the unknown: <https://pubmed.ncbi.nlm.nih.gov/33527524/>

Cutaneous adverse effects of available COVID-19 vaccines: <https://pubmed.ncbi.nlm.nih.gov/34518015/>

Cumulative adverse event report of anaphylaxis following injections of COVID-19 mRNA vaccine (Pfizer-BioNTech) in Japan: the first month report: <https://pubmed.ncbi.nlm.nih.gov/34347278/>

COVID-19 vaccines increase the risk of anaphylaxis: <https://pubmed.ncbi.nlm.nih.gov/33685103/>

Biphasic anaphylaxis after exposure to the first dose of the Pfizer-BioNTech COVID-19 mRNA vaccine COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34050949/>

Allergenic components of the mRNA-1273 vaccine for COVID-19: possible involvement of polyethylene glycol and IgG-mediated complement activation: <https://pubmed.ncbi.nlm.nih.gov/33657648/>

Polyethylene glycol (PEG) is a cause of anaphylaxis to Pfizer / BioNTech mRNA COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33825239/>

Acute allergic reactions to COVID-19 mRNA vaccines: <https://pubmed.ncbi.nlm.nih.gov/33683290/>

Polyethylene glycole allergy of the SARS CoV2 vaccine recipient: case report of a young adult recipient and management of future exposure to SARS-CoV2: <https://pubmed.ncbi.nlm.nih.gov/33919151/>

Elevated rates of anaphylaxis after vaccination with Pfizer BNT162b2 mRNA vaccine against COVID-19 in Japanese healthcare workers; a secondary analysis of initial post-approval safety data: <https://pubmed.ncbi.nlm.nih.gov/34128049/>

Allergic reactions and adverse events associated with administration of mRNA-based vaccines. A health system experience: <https://pubmed.ncbi.nlm.nih.gov/34474708/>

Allergic reactions to COVID-19 vaccines: statement of the Belgian Society of Allergy and Clinical Immunology (BelSACI): <https://www.tandfonline.com/doi/abs/10.1080/17843286.2021.1909447>

.IgE-mediated allergy to polyethylene glycol (PEG) as a cause of anaphylaxis to COVID-19 mRNA vaccines: <https://pubmed.ncbi.nlm.nih.gov/34318537/>

Allergic reactions after COVID-19 vaccination: putting the risk in perspective: <https://pubmed.ncbi.nlm.nih.gov/34463751/>

Anaphylactic reactions to COVID-19 mRNA vaccines: a call for further studies: <https://pubmed.ncbi.nlm.nih.gov/33846043/> 188.

Risk of severe allergic reactions to COVID-19 vaccines among patients with allergic skin disease: practical recommendations. An ETFAD position statement with external experts: <https://pubmed.ncbi.nlm.nih.gov/33752263/>

COVID-19 vaccine and death: causality algorithm according to the WHO eligibility diagnosis: <https://pubmed.ncbi.nlm.nih.gov/34073536/>

Fatal brain hemorrhage after COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33928772/>

A case series of skin reactions to COVID-19 vaccine in the Department of Dermatology at Loma Linda University: <https://pubmed.ncbi.nlm.nih.gov/34423106/>

Skin reactions reported after Moderna and Pfizer's COVID-19 vaccination: a study based on a registry of 414 cases: <https://pubmed.ncbi.nlm.nih.gov/33838206/>

Clinical and pathologic correlates of skin reactions to COVID-19 vaccine, including V-REPP: a registry-based study: <https://pubmed.ncbi.nlm.nih.gov/34517079/>

Skin reactions after vaccination against SARS-COV-2: a nationwide Spanish cross-sectional study of 405 cases: <https://pubmed.ncbi.nlm.nih.gov/34254291/>

Varicella zoster virus and herpes simplex virus reactivation after vaccination with COVID-19: review of 40 cases in an international dermatologic registry: <https://pubmed.ncbi.nlm.nih.gov/34487581/>

Immune thrombosis and thrombocytopenia (VITT) associated with the COVID-19 vaccine: diagnostic and therapeutic recommendations for a new syndrome: <https://pubmed.ncbi.nlm.nih.gov/33987882/>

Laboratory testing for suspicion of COVID-19 vaccine-induced thrombotic (immune) thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34138513/>

Intracerebral hemorrhage due to thrombosis with thrombocytopenia syndrome after COVID-19 vaccination: the first fatal case in Korea: <https://pubmed.ncbi.nlm.nih.gov/34402235/>

Risk of thrombocytopenia and thromboembolism after covid-19 vaccination and positive SARS-CoV-2 tests: self-controlled case series study: <https://pubmed.ncbi.nlm.nih.gov/34446426/>

Vaccine-induced immune thrombotic thrombocytopenia and cerebral venous sinus thrombosis after covid-19 vaccination; a systematic review: <https://pubmed.ncbi.nlm.nih.gov/34365148/>.

Nerve and muscle adverse events after vaccination with COVID-19: a systematic review and meta-analysis of clinical trials: <https://pubmed.ncbi.nlm.nih.gov/34452064/>.

A rare case of cerebral venous thrombosis and disseminated intravascular coagulation temporally associated with administration of COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33917902/>

Primary adrenal insufficiency associated with thrombotic immune thrombocytopenia induced by Oxford-AstraZeneca ChAdOx1 nCoV-19 vaccine (VITT): <https://pubmed.ncbi.nlm.nih.gov/34256983/>

Acute cerebral venous thrombosis and pulmonary artery embolism associated with the COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34247246/>.

Thromboaspiration infusion and fibrinolysis for portomesenteric thrombosis after administration of AstraZeneca COVID-19

vaccine: <https://pubmed.ncbi.nlm.nih.gov/34132839/>

59-year-old woman with extensive deep venous thrombosis and pulmonary thromboembolism 7 days after a first dose of Pfizer-BioNTech BNT162b2 mRNA vaccine COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34117206/>

Cerebral venous thrombosis and vaccine-induced thrombocytopenia.a. Oxford-AstraZeneca COVID-19: a missed opportunity for a rapid return on experience: <https://pubmed.ncbi.nlm.nih.gov/34033927/>

Myocarditis and other cardiovascular complications of mRNA-based COVID-19 vaccines: <https://pubmed.ncbi.nlm.nih.gov/34277198/>

Pericarditis after administration of COVID-19 mRNA BNT162b2 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34364831/>

Unusual presentation of acute pericarditis after vaccination against SARS-COV-2 mRNA-1237 Modern: <https://pubmed.ncbi.nlm.nih.gov/34447639/>

Case report: acute myocarditis after second dose of SARS-CoV-2 mRNA-1273 vaccine mRNA-1273: <https://pubmed.ncbi.nlm.nih.gov/34514306/>

Immune-mediated disease outbreaks or recent-onset disease in 27 subjects after mRNA/DNA vaccination against SARS-CoV-2: <https://pubmed.ncbi.nlm.nih.gov/33946748/>

Insights from a murine model of myopericarditis induced by COVID-19 mRNA vaccine: could accidental intravenous injection of a vaccine induce myopericarditis: <https://pubmed.ncbi.nlm.nih.gov/34453510/>

Immune thrombocytopenia in a 22-year-old post Covid-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33476455/>

propylthiouracil-induced neutrophil anti-cytoplasmic antibody-associated vasculitis after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34451967/>

Secondary immune thrombocytopenia (ITP) associated with ChAdOx1 Covid-19 vaccine: case report: <https://pubmed.ncbi.nlm.nih.gov/34377889/>

Thrombosis with thrombocytopenia syndrome (TTS) following AstraZeneca ChAdOx1 nCoV-19 (AZD1222) COVID-19 vaccination: risk-benefit analysis for persons <60 years in Australia: <https://pubmed.ncbi.nlm.nih.gov/34272095/>

COVID-19 vaccination association and facial nerve palsy: A case-control study: <https://pubmed.ncbi.nlm.nih.gov/34165512/>

The association between COVID-19 vaccination and Bell's palsy: <https://pubmed.ncbi.nlm.nih.gov/34411533/>

Bell's palsy after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33611630/>

Acute transverse myelitis (ATM): clinical review of 43 patients with COVID-19-associated ATM and 3 serious adverse events of post-vaccination ATM with ChAdOx1 nCoV-19 vaccine (AZD1222): <https://pubmed.ncbi.nlm.nih.gov/33981305/>

Bell's palsy after 24 hours of mRNA-1273 SARS-CoV-2 mRNA-1273 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34336436/>

Sequential contralateral facial nerve palsy after first and second doses of COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34281950/>.

Transverse myelitis induced by SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34458035/>

Peripheral facial nerve palsy after vaccination with BNT162b2 (COVID-19): <https://pubmed.ncbi.nlm.nih.gov/33734623/>

Acute abducens nerve palsy after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34044114/>.

Facial nerve palsy after administration of COVID-19 mRNA vaccines: analysis of self-report database: <https://pubmed.ncbi.nlm.nih.gov/34492394/>

Transient oculomotor paralysis after administration of RNA-1273 messenger vaccine for SARS-CoV-2 diplopia after COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34369471/>

Bell's palsy after Ad26.COV2.S COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34014316/>

Bell's palsy after COVID-19 vaccination: case report: <https://pubmed.ncbi.nlm.nih.gov/34330676/>

A case of acute demyelinating polyradiculoneuropathy with bilateral facial palsy following ChAdOx1 nCoV-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34272622/>

Guillain Barré syndrome after vaccination with mRNA-1273 against COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34477091/>

Acute facial paralysis as a possible complication of SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33975372/>.

Bell's palsy after COVID-19 vaccination with high antibody response in CSF: <https://pubmed.ncbi.nlm.nih.gov/34322761/>.

Parsonage-Turner syndrome associated with SARS-CoV-2 or SARS-CoV-2 vaccination. Comment on: "Neuralgic amyotrophy and COVID-19 infection: 2 cases of accessory spinal nerve palsy" by Coll et al. Articular Spine 2021; 88: 10519: <https://pubmed.ncbi.nlm.nih.gov/34139321/>.

Bell's palsy after a single dose of vaccine mRNA. SARS-CoV-2: case report: <https://pubmed.ncbi.nlm.nih.gov/34032902/>.

Autoimmune hepatitis developing after coronavirus disease vaccine 2019 (COVID-19): causality or victim?: <https://pubmed.ncbi.nlm.nih.gov/33862041/>

Autoimmune hepatitis triggered by vaccination against SARS-CoV-2: <https://pubmed.ncbi.nlm.nih.gov/34332438/>

Acute autoimmune-like hepatitis with atypical antimitochondrial antibody after vaccination with COVID-19 mRNA: a new clinical entity: <https://pubmed.ncbi.nlm.nih.gov/34293683/>.

Autoimmune hepatitis after COVID vaccine: <https://pubmed.ncbi.nlm.nih.gov/34225251/>

A novel case of bifacial diplegia variant of Guillain-Barré syndrome after vaccination with Janssen COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34449715/>

Comparison of vaccine-induced thrombotic events between ChAdOx1 nCoV-19 and Ad26.COV.2.S vaccines: <https://pubmed.ncbi.nlm.nih.gov/34139631/>.

Bilateral superior ophthalmic vein thrombosis, ischemic stroke and immune thrombocytopenia after vaccination with ChAdOx1 nCoV-

19: <https://pubmed.ncbi.nlm.nih.gov/33864750/>

Diagnosis and treatment of cerebral venous sinus thrombosis with vaccine-induced immune-immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/33914590/>

Venous sinus thrombosis after vaccination with ChAdOx1 nCov-

19: <https://pubmed.ncbi.nlm.nih.gov/34420802/>

Cerebral venous sinus thrombosis following vaccination against SARS-CoV-2: an analysis of cases reported to the European Medicines

Agency: <https://pubmed.ncbi.nlm.nih.gov/34293217/>

Risk of thrombocytopenia and thromboembolism after covid-19 vaccination and positive SARS-CoV-2 tests: self-controlled case series

study: <https://pubmed.ncbi.nlm.nih.gov/34446426/>

Blood clots and bleeding after BNT162b2 and ChAdOx1 nCoV-19 vaccination: an analysis of European data: <https://pubmed.ncbi.nlm.nih.gov/34174723/>

Arterial events, venous thromboembolism, thrombocytopenia and bleeding after vaccination with Oxford-AstraZeneca ChAdOx1-S in Denmark and Norway: population-based cohort

study: <https://pubmed.ncbi.nlm.nih.gov/33952445/>

First dose of ChAdOx1 and BNT162b2 COVID-19 vaccines and thrombocytopenic, thromboembolic and hemorrhagic events in

Scotland: <https://pubmed.ncbi.nlm.nih.gov/34108714/>

Cerebral venous thrombosis associated with COVID-19 vaccine in

Germany: <https://pubmed.ncbi.nlm.nih.gov/34288044/>

Malignant cerebral infarction after vaccination with ChAdOx1 nCov-19: a catastrophic variant of vaccine-induced immune-mediated thrombotic

thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34341358/>

celiac artery and splenic artery thrombosis complicated by splenic infarction 7 days after the first dose of Oxford vaccine, causal relationship or

coincidence: <https://pubmed.ncbi.nlm.nih.gov/34261633/>.

Primary adrenal insufficiency associated with Oxford-AstraZeneca ChAdOx1 nCoV-19 (VITT) vaccine-induced immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34256983/>

Thrombocytopenia after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34332437/>.

Cerebral venous sinus thrombosis associated with thrombocytopenia after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33845870/>.

Thrombosis with thrombocytopenia syndrome after COVID-19 immunization: <https://pubmed.ncbi.nlm.nih.gov/34236343/>

Acute myocardial infarction within 24 hours after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34364657/>.

Bilateral acute macular neuroretinopathy after SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34287612/>

central venous sinus thrombosis with subarachnoid hemorrhage after COVID-19 mRNA vaccination: are these reports merely coincidental: <https://pubmed.ncbi.nlm.nih.gov/34478433/>

Intracerebral hemorrhage due to thrombosis with thrombocytopenia syndrome after COVID-19 vaccination: the first fatal case in Korea: <https://pubmed.ncbi.nlm.nih.gov/34402235/>

Cerebral venous sinus thrombosis negative for anti-PF4 antibody without thrombocytopenia after immunization with COVID-19 vaccine in a non-comorbid elderly Indian male treated with conventional heparin-warfarin-based anticoagulation: <https://pubmed.ncbi.nlm.nih.gov/34186376/>

Cerebral venous sinus thrombosis 2 weeks after first dose of SARS-CoV-2 mRNA vaccine: <https://pubmed.ncbi.nlm.nih.gov/34101024/>

A case of multiple thrombocytopenia and thrombosis following vaccination with ChAdOx1 nCoV-19 against SARS-CoV-2: <https://pubmed.ncbi.nlm.nih.gov/34137813/>

Vaccine-induced thrombotic thrombocytopenia: the elusive link between thrombosis and adenovirus-based SARS-CoV-2 vaccines: <https://pubmed.ncbi.nlm.nih.gov/34191218/>

Acute ischemic stroke revealing immune thrombotic thrombocytopenia induced by ChAdOx1 nCov-19 vaccine: impact on recanalization strategy: <https://pubmed.ncbi.nlm.nih.gov/34175640/>

New-onset refractory status epilepticus after ChAdOx1 nCoV-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34153802/>

Thrombosis with thrombocytopenia syndrome associated with COVID-19 viral vector vaccines: <https://pubmed.ncbi.nlm.nih.gov/34092488/>

Pulmonary embolism, transient ischemic attack, and thrombocytopenia after Johnson & Johnson COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34261635/>

Thromboaspiration infusion and fibrinolysis for portomesenteric thrombosis after administration of the AstraZeneca COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34132839/>.

Spontaneous HIT syndrome: knee replacement, infection, and parallels with vaccine-induced immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34144250/>

Deep venous thrombosis (DVT) occurring shortly after second dose of SARS-CoV-2 mRNA vaccine: <https://pubmed.ncbi.nlm.nih.gov/33687691/>

Procoagulant antibody-mediated procoagulant platelets in immune thrombotic thrombocytopenia associated with SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34011137/>.

Vaccine-induced immune thrombotic thrombocytopenia causing a severe form of cerebral venous thrombosis with high mortality rate: a case series: <https://pubmed.ncbi.nlm.nih.gov/34393988/>.

Procoagulant microparticles: a possible link between vaccine-induced immune thrombocytopenia (VITT) and cerebral sinus venous thrombosis: <https://pubmed.ncbi.nlm.nih.gov/34129181/>.

Atypical thrombosis associated with the vaccine VaxZevria® (AstraZeneca): data from the French network of regional pharmacovigilance centers: <https://pubmed.ncbi.nlm.nih.gov/34083026/>.

Acute cerebral venous thrombosis and pulmonary artery embolism associated with the COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34247246/>.

Vaccine-induced thrombosis and thrombocytopenia with bilateral adrenal haemorrhage: <https://pubmed.ncbi.nlm.nih.gov/34235757/>.

Palmar digital vein thrombosis after Oxford-AstraZeneca COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34473841/>.

Cutaneous thrombosis associated with cutaneous necrosis following Oxford-AstraZeneca COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34189756/>

Cerebral venous thrombosis following COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34045111/>.

Lipschütz ulcers after AstraZeneca COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34366434/>.

Amyotrophic Neuralgia secondary to Vaxzevri vaccine (AstraZeneca) COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34330677/>

Thrombosis with thrombocytopenia after Messenger vaccine RNA-1273: <https://pubmed.ncbi.nlm.nih.gov/34181446/>

Intracerebral hemorrhage twelve days after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34477089/>

Thrombotic thrombocytopenia after vaccination with COVID-19: in search of the underlying mechanism: <https://pubmed.ncbi.nlm.nih.gov/34071883/>

Coronavirus (COVID-19) Vaccine-induced immune thrombotic thrombocytopenia (VITT): <https://pubmed.ncbi.nlm.nih.gov/34033367/>

Comparison of adverse drug reactions among four COVID-19 vaccines in Europe using the EudraVigilance database: Thrombosis in unusual sites: <https://pubmed.ncbi.nlm.nih.gov/34375510/>

Immunoglobulin adjuvant for vaccine-induced immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34107198/>

Severe vaccine-induced thrombotic thrombocytopenia following vaccination with COVID-19: an autopsy case report and review of the literature: <https://pubmed.ncbi.nlm.nih.gov/34355379/>.

A case of acute pulmonary embolism after immunization with SARS-CoV-2 mRNA: <https://pubmed.ncbi.nlm.nih.gov/34452028/>

Neurosurgical considerations regarding decompressive craniectomy for intracerebral hemorrhage after SARS-CoV-2 vaccination in vaccine-induced thrombotic thrombocytopenia-VITT: <https://pubmed.ncbi.nlm.nih.gov/34202817/>

Thrombosis and SARS-CoV-2 vaccines: vaccine-induced immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34237213/>.

Acquired thrombotic thrombocytopenic thrombocytopenic purpura: a rare disease associated with the BNT162b2 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34105247/>.

Immune complexes, innate immunity and NETosis in ChAdOx1 vaccine-induced thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34405870/>.

Sensory Guillain-Barré syndrome following ChAdOx1 nCov-19 vaccine: report of two cases and review of the literature: <https://pubmed.ncbi.nlm.nih.gov/34416410/>.

Vogt-Koyanagi-Harada syndrome after COVID-19 and ChAdOx1 nCoV-19 (AZD1222) vaccination: <https://pubmed.ncbi.nlm.nih.gov/34462013/>.

Reactivation of Vogt-Koyanagi-Harada disease under control for more than 6 years, after anti-SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34224024/>.

Post-vaccinal encephalitis after ChAdOx1 nCov-19: <https://pubmed.ncbi.nlm.nih.gov/34324214/>

Neurological symptoms and neuroimaging alterations related to COVID-19 vaccine: cause or coincidence?: <https://pubmed.ncbi.nlm.nih.gov/34507266/>

Fatal systemic capillary leak syndrome after SARS-COV-2 vaccination in a patient with multiple myeloma: <https://pubmed.ncbi.nlm.nih.gov/34459725/>

Polyarthralgia and myalgia syndrome after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34463066/>

Three cases of subacute thyroiditis after SARS-CoV-2 vaccination: post-vaccination ASIA syndrome: <https://pubmed.ncbi.nlm.nih.gov/34043800/>.

Facial diplegia: a rare and atypical variant of Guillain-Barré syndrome and the Ad26.COV2.S vaccine: <https://pubmed.ncbi.nlm.nih.gov/34447646/>

Association between ChAdOx1 nCoV-19 vaccination and bleeding episodes: large population-based cohort study: <https://pubmed.ncbi.nlm.nih.gov/34479760/>.

fulminant myocarditis and systemic hyperinflammation temporally associated with BNT162b2 COVID-19 mRNA vaccination in two patients: <https://pubmed.ncbi.nlm.nih.gov/34416319/>.

Adverse effects reported after COVID-19 vaccination in a tertiary care hospital, centered on cerebral venous sinus thrombosis (CVST): <https://pubmed.ncbi.nlm.nih.gov/34092166/>

Induction and exacerbation of subacute cutaneous lupus erythematosus erythematosus after mRNA- or adenoviral vector-based SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34291477/>

Petechiae and peeling of fingers after immunization with BTN162b2 messenger RNA (mRNA)-based COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34513435/>

Hepatitis C virus reactivation after COVID-19 vaccination: a case report: <https://pubmed.ncbi.nlm.nih.gov/34512037/>

Bilateral immune-mediated keratolysis after immunization with SARS-CoV-2 recombinant viral vector vaccine: <https://pubmed.ncbi.nlm.nih.gov/34483273/>.

Immune-mediated thrombocytopenic purpura after Pfizer-BioNTech COVID-19 vaccine in an elderly woman: <https://pubmed.ncbi.nlm.nih.gov/34513446/>

Platelet activation and modulation in thrombosis with thrombocytopenia syndrome associated with the ChAdO × 1 nCov-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34474550/>

Reactive arthritis after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34033732/>.

Two cases of Graves' disease after SARS-CoV-2 vaccination: an autoimmune / inflammatory syndrome induced by adjuvants: <https://pubmed.ncbi.nlm.nih.gov/33858208/>

Acute relapse and impaired immunization after COVID-19 vaccination in a patient with multiple sclerosis treated with rituximab: <https://pubmed.ncbi.nlm.nih.gov/34015240/>

Widespread fixed bullous drug eruption after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34482558/>

COVID-19 mRNA vaccine causing CNS inflammation: a case series: <https://pubmed.ncbi.nlm.nih.gov/34480607/>

Thymic hyperplasia after Covid-19 mRNA-based vaccination with Covid-19: <https://pubmed.ncbi.nlm.nih.gov/34462647/>

Acute disseminated encephalomyelitis following vaccination against SARS-CoV-2: <https://pubmed.ncbi.nlm.nih.gov/34325334/>

Tolosa-Hunt syndrome occurring after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34513398/>

Systemic capillary extravasation syndrome following vaccination with ChAdOx1 nCoV-19 (Oxford-AstraZeneca): <https://pubmed.ncbi.nlm.nih.gov/34362727/>

Immune-mediated thrombocytopenia associated with Ad26.COV2.S vaccine (Janssen; Johnson & Johnson): <https://pubmed.ncbi.nlm.nih.gov/34469919/>.

Transient thrombocytopenia with glycoprotein-specific platelet autoantibodies after vaccination with Ad26.COV2.S: case report: <https://pubmed.ncbi.nlm.nih.gov/34516272/>.

Acute hyperactive encephalopathy following COVID-19 vaccination with dramatic response to methylprednisolone: case report: <https://pubmed.ncbi.nlm.nih.gov/34512961/>

Transient cardiac injury in adolescents receiving the BNT162b2 mRNA COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34077949/>

Autoimmune hepatitis developing after ChAdOx1 nCoV-19 vaccine (Oxford-AstraZeneca): <https://pubmed.ncbi.nlm.nih.gov/34171435/>

Severe relapse of multiple sclerosis after COVID-19 vaccination: a case report: <https://pubmed.ncbi.nlm.nih.gov/34447349/>

Lymphohistocytic myocarditis after vaccination with the COVID-19 viral vector Ad26.COV2.S: <https://pubmed.ncbi.nlm.nih.gov/34514078/>

Hemophagocytic lymphohistiocytosis after vaccination with ChAdOx1 nCov-19: <https://pubmed.ncbi.nlm.nih.gov/34406660/>.

IgA vasculitis in adult patient after vaccination with ChadOx1 nCoV-

19: <https://pubmed.ncbi.nlm.nih.gov/34509658/>

A case of leukocytoclastic vasculitis after vaccination with a SARS-CoV2 vaccine: case report: <https://pubmed.ncbi.nlm.nih.gov/34196469/>.

Onset / outbreak of psoriasis after Corona virus ChAdOx1 nCoV-19 vaccine (Oxford-AstraZeneca / Covishield): report of two cases: <https://pubmed.ncbi.nlm.nih.gov/34350668/>

Hailey-Hailey disease exacerbation after SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34436620/>

Supraclavicular lymphadenopathy after COVID-19 vaccination in Korea: serial follow-up by ultrasonography: <https://pubmed.ncbi.nlm.nih.gov/34116295/>.

COVID-19 vaccine, immune thrombotic thrombocytopenia, jaundice, hyperviscosity: concern in cases with underlying hepatic problems: <https://pubmed.ncbi.nlm.nih.gov/34509271/>.

Report of the International Cerebral Venous Thrombosis Consortium on cerebral venous thrombosis after SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34462996/>

Immune thrombocytopenia after vaccination during the COVID-19 pandemic: <https://pubmed.ncbi.nlm.nih.gov/34435486/>

COVID-19: lessons from the Norwegian tragedy should be taken into account in planning for vaccine launch in less developed/developing countries: <https://pubmed.ncbi.nlm.nih.gov/34435142/>

Rituximab-induced acute lympholysis and pancytopenia following vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34429981/>

Exacerbation of plaque psoriasis after COVID-19 inactivated mRNA and BNT162b2 vaccines: report of two cases: <https://pubmed.ncbi.nlm.nih.gov/34427024/>

Vaccine-induced interstitial lung disease: a rare reaction to COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34510014/>.

Vesiculobullous cutaneous reactions induced by COVID-19 mRNA vaccine: report of four cases and review of the literature: <https://pubmed.ncbi.nlm.nih.gov/34236711/>

Vaccine-induced thrombocytopenia with severe headache: <https://pubmed.ncbi.nlm.nih.gov/34525282/>

Acute perimyocarditis after the first dose of COVID-19 mRNA vaccine: <https://pubmed.ncbi.nlm.nih.gov/34515024/>

Rhabdomyolysis and fasciitis induced by COVID-19 mRNA vaccine: <https://pubmed.ncbi.nlm.nih.gov/34435250/>.

Rare cutaneous adverse effects of COVID-19 vaccines: a case series and review of the literature: <https://pubmed.ncbi.nlm.nih.gov/34363637/>

Immune thrombocytopenia associated with the Pfizer-BioNTech COVID-19 mRNA vaccine BNT162b2: <https://www.sciencedirect.com/science/article/pii/S2214250921002018>

Secondary immune thrombocytopenia putatively attributable to COVID-19 vaccination: <https://casereports.bmj.com/content/14/5/e242220.abstract>.

Immune thrombocytopenia following Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34155844/>

Newly diagnosed idiopathic thrombocytopenia after COVID-19 vaccine administration: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8176657/>.

Idiopathic thrombocytopenic purpura and the Modern Covid-19 vaccine: [https://www.annemergmed.com/article/S0196-0644\(21\)00122-0/fulltext](https://www.annemergmed.com/article/S0196-0644(21)00122-0/fulltext).

Thrombocytopenia after Pfizer and Moderna SARS vaccination – CoV - 2: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8014568/>.

Immune thrombocytopenic purpura and acute liver injury after COVID-19 vaccination: <https://casereports.bmj.com/content/14/7/e242678>.

Collection of complement-mediated and autoimmune-mediated hematologic conditions after SARS-CoV-2 vaccination: <https://ashpublications.org/bloodadvances/article/5/13/2794/476324/Autoimmune-and-complement-mediated-hematologic>

Petechial rash associated with CoronaVac vaccination: first report of cutaneous side effects before phase 3 results: <https://ejhp.bmj.com/content/early/2021/05/23/ejhpharm-2021-002794>

COVID-19 vaccines induce severe hemolysis in paroxysmal nocturnal hemoglobinuria: <https://ashpublications.org/blood/article/137/26/3670/475905/COVID-19-vaccines-induce-severe-hemolysis-in>

Cerebral venous thrombosis associated with COVID-19 vaccine in Germany: <https://pubmed.ncbi.nlm.nih.gov/34288044/>.

Cerebral venous sinus thrombosis after COVID-19 vaccination : Neurological and radiological management: <https://pubmed.ncbi.nlm.nih.gov/34327553/>.

Cerebral venous thrombosis and thrombocytopenia after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33878469/>.

Cerebral venous sinus thrombosis and thrombocytopenia after COVID-19 vaccination: report of two cases in the United Kingdom: <https://pubmed.ncbi.nlm.nih.gov/33857630/>.

Cerebral venous thrombosis induced by SARS-CoV-2 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34090750/>.

Carotid artery immune thrombosis induced by adenovirus-vectored COVID-19 vaccine: case report: <https://pubmed.ncbi.nlm.nih.gov/34312301/>.

Cerebral venous sinus thrombosis associated with vaccine-induced thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34333995/>

The roles of platelets in COVID-19-associated coagulopathy and vaccine-induced immune-immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34455073/>

Cerebral venous thrombosis after the BNT162b2 mRNA SARS-CoV-2 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34111775/>.

Cerebral venous thrombosis after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34045111/>

Lethal cerebral venous sinus thrombosis after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33983464/>

Cerebral venous sinus thrombosis in the U.S. population, After SARS-CoV-2 vaccination with adenovirus and after COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34116145/>

Cerebral venous thrombosis after COVID-19 vaccination: is the risk of thrombosis increased by intravascular administration of the vaccine: <https://pubmed.ncbi.nlm.nih.gov/34286453/>.

Central venous sinus thrombosis with subarachnoid hemorrhage after COVID-19 mRNA vaccination: are these reports merely coincidental: <https://pubmed.ncbi.nlm.nih.gov/34478433/>

Cerebral venous sinus thrombosis after ChAdOx1 nCov-19 vaccination with a misleading first brain MRI: <https://pubmed.ncbi.nlm.nih.gov/34244448/>

Early results of bivalirudin treatment for thrombotic thrombocytopenia and cerebral venous sinus thrombosis after vaccination with Ad26.COV2.S: <https://pubmed.ncbi.nlm.nih.gov/34226070/>

Cerebral venous sinus thrombosis associated with post-vaccination thrombocytopenia by COVID-19: <https://pubmed.ncbi.nlm.nih.gov/33845870/>.

Cerebral venous sinus thrombosis 2 weeks after the first dose of SARS-CoV-2 mRNA vaccine: <https://pubmed.ncbi.nlm.nih.gov/34101024/>.

Vaccine-induced immune thrombotic thrombocytopenia causing a severe form of cerebral venous thrombosis with a high mortality rate: a case series: <https://pubmed.ncbi.nlm.nih.gov/34393988/>.

Adenovirus interactions with platelets and coagulation and vaccine-associated autoimmune thrombocytopenia thrombosis syndrome: <https://pubmed.ncbi.nlm.nih.gov/34407607/>.

Headache attributed to COVID-19 (SARS-CoV-2 coronavirus) vaccination with the ChAdOx1 nCoV-19 (AZD1222) vaccine: a multicenter observational cohort study: <https://pubmed.ncbi.nlm.nih.gov/34313952/>

Adverse effects reported after COVID-19 vaccination in a tertiary care hospital, focus on cerebral venous sinus thrombosis (CVST): <https://pubmed.ncbi.nlm.nih.gov/34092166/>

Cerebral venous sinus thrombosis following vaccination against SARS-CoV-2: an analysis of cases reported to the European Medicines Agency: <https://pubmed.ncbi.nlm.nih.gov/34293217/>

A rare case of a middle-age Asian male with cerebral venous thrombosis after COVID-19 AstraZeneca vaccination: <https://pubmed.ncbi.nlm.nih.gov/34274191/>

Cerebral venous sinus thrombosis negative for anti-PF4 antibody without thrombocytopenia after immunization with COVID-19 vaccine in a non-comorbid elderly Indian male treated with conventional heparin-warfarin-based anticoagulation: <https://pubmed.ncbi.nlm.nih.gov/34186376/>

Arterial events, venous thromboembolism, thrombocytopenia and bleeding after vaccination with Oxford-AstraZeneca ChAdOx1-S in Denmark and Norway: population-based cohort study: <https://pubmed.ncbi.nlm.nih.gov/33952445/>

Procoagulant microparticles: a possible link between vaccine-induced immune thrombocytopenia (VITT) and cerebral sinus venous thrombosis: <https://pubmed.ncbi.nlm.nih.gov/34129181/>

U.S. case reports of cerebral venous sinus thrombosis with thrombocytopenia after vaccination with Ad26.COV2.S, March 2-April 21, 2021: <https://pubmed.ncbi.nlm.nih.gov/33929487/>.

Malignant cerebral infarction after vaccination with ChAdOx1 nCov-19: a catastrophic variant of vaccine-induced immune-mediated thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34341358/>

Acute ischemic stroke revealing immune thrombotic thrombocytopenia induced by ChAdOx1 nCov-19 vaccine: impact on recanalization strategy: <https://pubmed.ncbi.nlm.nih.gov/34175640/>

Vaccine-induced immune thrombotic immune thrombocytopenia (VITT): a new clinicopathologic entity with heterogeneous clinical presentations: <https://pubmed.ncbi.nlm.nih.gov/34159588/>.

Imaging and hematologic findings in thrombosis and thrombocytopenia after vaccination with ChAdOx1 nCoV-19 (AstraZeneca): <https://pubmed.ncbi.nlm.nih.gov/34402666/>

Autoimmunity roots of thrombotic events after vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34508917/>

Cerebral venous sinus thrombosis after vaccination: the UK experience: <https://pubmed.ncbi.nlm.nih.gov/34370974/>

Massive cerebral venous thrombosis and venous basin infarction as late complications of COVID-19: a case report: <https://pubmed.ncbi.nlm.nih.gov/34373991/>

Australian and New Zealand approach to the diagnosis and treatment of vaccine-induced immune thrombosis and immune thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34490632/>

An observational study to identify the prevalence of thrombocytopenia and anti-PF4 / polyanion antibodies in Norwegian health care workers after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33909350/>

Acute transverse myelitis (ATM): clinical review of 43 patients with COVID-19-associated ATM and 3 serious adverse events of post-vaccination ATM with ChAdOx1 nCoV-19 (AZD1222) vaccine: <https://pubmed.ncbi.nlm.nih.gov/33981305/>.

A case of acute demyelinating polyradiculoneuropathy with bilateral facial palsy after ChAdOx1 nCoV-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34272622/>

Thrombocytopenia with acute ischemic stroke and hemorrhage in a patient recently vaccinated with an adenoviral vector-based COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33877737/>

Predicted and observed incidence of thromboembolic events among Koreans vaccinated with the ChAdOx1 nCoV-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34254476/>

First dose of ChAdOx1 and BNT162b2 COVID-19 vaccines and thrombocytopenic, thromboembolic, and hemorrhagic events in Scotland: <https://pubmed.ncbi.nlm.nih.gov/34108714/>

ChAdOx1 nCoV-19 vaccine-associated thrombocytopenia: three cases of immune thrombocytopenia after 107,720 doses of ChAdOx1 vaccination in Thailand: <https://pubmed.ncbi.nlm.nih.gov/34483267/>.

Pulmonary embolism, transient ischemic attack, and thrombocytopenia after Johnson & Johnson COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34261635/>

Neurosurgical considerations with respect to decompressive craniectomy for intracerebral hemorrhage after SARS-CoV-2 vaccination in vaccine-induced thrombotic thrombocytopenia-VITT: <https://pubmed.ncbi.nlm.nih.gov/34202817/>

Large hemorrhagic stroke after vaccination against ChAdOx1 nCoV-19: a case report: <https://pubmed.ncbi.nlm.nih.gov/34273119/>

Polyarthralgia and myalgia syndrome after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34463066/>

A rare case of thrombosis and thrombocytopenia of the superior ophthalmic vein after ChAdOx1 nCoV-19 vaccination against SARS-CoV-2: <https://pubmed.ncbi.nlm.nih.gov/34276917/>

Thrombosis and severe acute respiratory syndrome Coronavirus 2 vaccines: vaccine-induced immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34237213/>.

Renal vein thrombosis and pulmonary embolism secondary to vaccine-induced thrombotic immune thrombocytopenia (VITT): <https://pubmed.ncbi.nlm.nih.gov/34268278/>.

Limb ischemia and pulmonary artery thrombosis after ChAdOx1 nCoV-19 vaccine (Oxford-AstraZeneca): a case of vaccine-induced immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/33990339/>.

Association between ChAdOx1 nCoV-19 vaccination and bleeding episodes: large population-based cohort study: <https://pubmed.ncbi.nlm.nih.gov/34479760/>.

Secondary thrombocytopenia after SARS-CoV-2 vaccination: case report of haemorrhage and hematoma after minor oral surgery: <https://pubmed.ncbi.nlm.nih.gov/34314875/>.

Venous thromboembolism and mild thrombocytopenia after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34384129/>

Fatal exacerbation of ChAdOx1-nCoV-19-induced thrombotic thrombocytopenia syndrome after successful initial therapy with intravenous immunoglobulins: a rationale for monitoring immunoglobulin G levels: <https://pubmed.ncbi.nlm.nih.gov/34382387/>

A case of ANCA-associated vasculitis after AZD1222 (Oxford-AstraZeneca) SARS-CoV-2 vaccination: victim or causality?: <https://pubmed.ncbi.nlm.nih.gov/34416184/>.

Intracerebral hemorrhage associated with vaccine-induced thrombotic thrombocytopenia after ChAdOx1 nCOVID-19 vaccination in a pregnant woman: <https://pubmed.ncbi.nlm.nih.gov/34261297/>

Massive cerebral venous thrombosis due to vaccine-induced immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34261296/>

Nephrotic syndrome after ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: <https://pubmed.ncbi.nlm.nih.gov/34250318/>.

A case of vaccine-induced immune-immune thrombotic thrombocytopenia with massive arteriovenous thrombosis: <https://pubmed.ncbi.nlm.nih.gov/34059191/>

Cutaneous thrombosis associated with cutaneous necrosis following Oxford-AstraZeneca COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34189756/>

Thrombocytopenia in an adolescent with sickle cell anemia after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34331506/>

Vaccine-induced thrombocytopenia with severe headache: <https://pubmed.ncbi.nlm.nih.gov/34525282/>

Myocarditis associated with SARS-CoV-2 mRNA vaccination in children aged 12 to 17 years: stratified analysis of a national database: <https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1>

COVID-19 mRNA vaccination and development of CMR-confirmed myopericarditis: <https://www.medrxiv.org/content/10.1101/2021.09.13.21262182v1.full?s=09>.

Severe autoimmune hemolytic anemia after receipt of SARS-CoV-2 mRNA vaccine: <https://onlinelibrary.wiley.com/doi/10.1111/trf.16672>

Intravenous injection of coronavirus disease 2019 (COVID-19) mRNA vaccine can induce acute myopericarditis in a mouse model: <https://t.co/j0IEM8cMXI>

A report of myocarditis adverse events in the U.S. Vaccine Adverse Event Reporting System. (VAERS) in association with COVID-19 injectable biologics: <https://pubmed.ncbi.nlm.nih.gov/34601006/>

This study concludes that: “The vaccine was associated with an excess risk of myocarditis (1 to 5 events per 100,000 persons). The risk of this potentially serious adverse event and of many other serious adverse events increased substantially after SARS-CoV-2 infection”: <https://www.nejm.org/doi/full/10.1056/NEJMoa2110475>

Bilateral uveitis after inoculation with COVID-19 vaccine: a case report: <https://www.sciencedirect.com/science/article/pii/S1201971221007797>

Myocarditis associated with SARS-CoV-2 mRNA vaccination in children aged 12 to 17 years: stratified analysis of a national database: <https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1>.

Immune-mediated hepatitis with the Moderna vaccine is no longer a coincidence but confirmed: <https://www.sciencedirect.com/science/article/pii/S0168827821020936>

Extensive investigations revealed consistent pathophysiologic alterations after vaccination with COVID-19 vaccines: <https://www.nature.com/articles/s41421-021-00329-3>

Lobar hemorrhage with ventricular rupture shortly after the first dose of an mRNA-based SARS-CoV-2 vaccine: <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8553377/>

Mrna COVID vaccines dramatically increase endothelial inflammatory markers and risk of Acute Coronary Syndrome as measured by PULS cardiac testing: a caution: https://www.ahajournals.org/doi/10.1161/circ.144.suppl_1.10712

ChAdOx1 interacts with CAR and PF4 with implications for thrombosis with thrombocytopenia syndrome: <https://www.science.org/doi/10.1126/sciadv.abl8213>

Lethal vaccine-induced immune thrombotic immune thrombocytopenia (VITT) following announcement 26.COVS.2: first documented case outside the U.S.: <https://pubmed.ncbi.nlm.nih.gov/34626338/>

A prothrombotic thrombocytopenic disorder resembling heparin-induced thrombocytopenia after coronavirus-19 vaccination: <https://europepmc.org/article/PPR/PPR304469435>.

VITT (vaccine-induced immune thrombotic thrombocytopenia) after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34731555/>

Vaccine-induced immune thrombotic thrombocytopenia (VITT): a new clinicopathologic entity with heterogeneous clinical presentations: <https://pubmed.ncbi.nlm.nih.gov/34159588/>

Treatment of acute ischemic stroke associated with ChAdOx1 nCoV-19 vaccine-induced immune thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34461442/>

Spectrum of neurological complications after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34719776/>.

Cerebral venous sinus thrombosis after vaccination: the UK experience: <https://pubmed.ncbi.nlm.nih.gov/34370974/>

Cerebral venous vein/venous sinus thrombosis with thrombocytopenia syndrome after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34373413/>

Portal vein thrombosis due to vaccine-induced immune thrombotic immune thrombocytopenia (VITT) after Covid vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34598301/>

Hematuria, a generalized petechial rash and headaches after Oxford AstraZeneca ChAdOx1 nCoV-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34620638/>

Myocardial infarction and azygos vein thrombosis after vaccination with ChAdOx1 nCoV-19 in a hemodialysis patient: <https://pubmed.ncbi.nlm.nih.gov/34650896/>

Takotsubo (stress) cardiomyopathy after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34625447/>

Humoral response induced by Prime-Boost vaccination with ChAdOx1 nCoV-19 and BNT162b2 mRNA vaccines in a patient with multiple sclerosis treated with teriflunomide: <https://pubmed.ncbi.nlm.nih.gov/34696248/>

Guillain-Barré syndrome after ChAdOx1 nCoV-19 COVID-19 vaccination: a case series: <https://pubmed.ncbi.nlm.nih.gov/34548920/>

Refractory vaccine-induced immune thrombotic thrombocytopenia (VITT) treated with delayed therapeutic plasma exchange (TPE): <https://pubmed.ncbi.nlm.nih.gov/34672380/>.

Rare case of COVID-19 vaccine-associated intracranial hemorrhage with venous sinus thrombosis: <https://pubmed.ncbi.nlm.nih.gov/34556531/>.

Delayed headache after COVID-19 vaccination: a warning sign for vaccine-induced cerebral venous thrombosis: <https://pubmed.ncbi.nlm.nih.gov/34535076/>.

Clinical features of vaccine-induced thrombocytopenia and immune thrombosis: <https://pubmed.ncbi.nlm.nih.gov/34379914/>.

Predictors of mortality in thrombotic thrombocytopenia after adenoviral COVID-19 vaccination: the FAPIC score: <https://pubmed.ncbi.nlm.nih.gov/34545400/>

Ischemic stroke as a presenting feature of immune thrombotic thrombocytopenia induced by ChAdOx1-nCoV-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34035134/>

In-hospital observational study of neurological disorders in patients recently vaccinated with COVID-19 mRNA vaccines: <https://pubmed.ncbi.nlm.nih.gov/34688190/>

Endovascular treatment for vaccine-induced cerebral venous sinus thrombosis and thrombocytopenia after vaccination with ChAdOx1 nCoV-19: report of three cases: <https://pubmed.ncbi.nlm.nih.gov/34782400/>

Cardiovascular, neurological, and pulmonary events after vaccination with BNT162b2, ChAdOx1 nCoV-19, and Ad26.COV2.S vaccines: an analysis of European data: <https://pubmed.ncbi.nlm.nih.gov/34710832/>

Cerebral venous thrombosis developing after vaccination. COVID-19: VITT, VATT, TTS and more: <https://pubmed.ncbi.nlm.nih.gov/34695859/>

Cerebral venous thrombosis and myeloproliferative neoplasms: a three-center study of 74 consecutive cases: <https://pubmed.ncbi.nlm.nih.gov/34453762/>.

Possible triggers of thrombocytopenia and/or hemorrhage by BNT162b2 vaccine, Pfizer-BioNTech: <https://pubmed.ncbi.nlm.nih.gov/34660652/>.

Multiple sites of arterial thrombosis in a 35-year-old patient after vaccination with ChAdOx1 (AstraZeneca), which required emergency femoral and carotid surgical thrombectomy: <https://pubmed.ncbi.nlm.nih.gov/34644642/>

Case series of vaccine-induced thrombotic thrombocytopenia in a London teaching hospital: <https://pubmed.ncbi.nlm.nih.gov/34694650/>

Neuro-ophthalmic complications with thrombocytopenia and thrombosis induced by ChAdOx1 nCoV-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34726934/>

Thrombotic events after COVID-19 vaccination in over 50 years of age: results of a population-based study in Italy: <https://pubmed.ncbi.nlm.nih.gov/34835237/>

Intracerebral hemorrhage associated with vaccine-induced thrombotic thrombocytopenia after ChAdOx1 nCOVID-19 vaccination in a pregnant woman: <https://pubmed.ncbi.nlm.nih.gov/34261297/>

Age- and sex-specific incidence of cerebral venous sinus thrombosis associated with Ad26.COV2.S COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34724036/>.

Genital necrosis with cutaneous thrombosis following vaccination with COVID-19 mRNA: <https://pubmed.ncbi.nlm.nih.gov/34839563/>

Cerebral venous sinus thrombosis after mRNA-based COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34783932/>.

COVID-19 vaccine-induced immune thrombosis with thrombocytopenia thrombosis (VITT) and shades of gray in thrombus formation: <https://pubmed.ncbi.nlm.nih.gov/34624910/>

Inflammatory myositis after vaccination with ChAdOx1: <https://pubmed.ncbi.nlm.nih.gov/34585145/>

Acute ST-segment elevation myocardial infarction secondary to vaccine-induced immune thrombosis with thrombocytopenia (VITT): <https://pubmed.ncbi.nlm.nih.gov/34580132/>.

A rare case of COVID-19 vaccine-induced thrombotic thrombocytopenia (VITT) affecting the venosplanchnic and pulmonary arterial circulation from a UK district general hospital: <https://pubmed.ncbi.nlm.nih.gov/34535492/>

COVID-19 vaccine-induced thrombotic thrombocytopenia: a case series: <https://pubmed.ncbi.nlm.nih.gov/34527501/>

Thrombosis with thrombocytopenia syndrome (TTS) after vaccination with AstraZeneca ChAdOx1 nCoV-19 (AZD1222) COVID-19: a risk-benefit analysis for persons <60% risk-benefit analysis for people <60 years in Australia: <https://pubmed.ncbi.nlm.nih.gov/34272095/>

Immune thrombocytopenia after immunization with Vaxzevria ChadOx1-S vaccine (AstraZeneca), Victoria, Australia: <https://pubmed.ncbi.nlm.nih.gov/34756770/>

Characteristics and outcomes of patients with cerebral venous sinus thrombosis in thrombotic immune thrombocytopenia induced by SARS-CoV-2 vaccine: <https://jamanetwork.com/journals/jamaneurology/fullarticle/2784622>

Case study of thrombosis and thrombocytopenia syndrome after administration of the AstraZeneca COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34781321/>

Thrombosis with Thrombocytopenia Syndrome Associated with COVID-19 Vaccines: <https://pubmed.ncbi.nlm.nih.gov/34062319/>

Cerebral venous sinus thrombosis following vaccination with ChAdOx1: the first case of definite thrombosis with thrombocytopenia syndrome in India: <https://pubmed.ncbi.nlm.nih.gov/34706921/>

COVID-19 vaccine-associated thrombosis with thrombocytopenia syndrome (TTS): systematic review and post hoc analysis: <https://pubmed.ncbi.nlm.nih.gov/34698582/>.

Case report of immune thrombocytopenia after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34751013/>.

Acute transverse myelitis after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34684047/>.

Concerns for adverse effects of thrombocytopenia and thrombosis after adenovirus-vectored COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34541935/>

Major hemorrhagic stroke after ChAdOx1 nCoV-19 vaccination: a case report: <https://pubmed.ncbi.nlm.nih.gov/34273119/>

Cerebral venous sinus thrombosis after COVID-19 vaccination: neurologic and radiologic management: <https://pubmed.ncbi.nlm.nih.gov/34327553/>.

Thrombocytopenia with acute ischemic stroke and hemorrhage in a patient recently vaccinated with an adenoviral vector-based COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33877737/>

Intracerebral hemorrhage and thrombocytopenia after AstraZeneca COVID-19 vaccine: clinical and diagnostic challenges of vaccine-induced thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34646685/>

Minimal change disease with severe acute kidney injury after Oxford-AstraZeneca COVID-19 vaccine: case report: <https://pubmed.ncbi.nlm.nih.gov/34242687/>.

Case report: cerebral sinus vein thrombosis in two patients with AstraZeneca SARS-CoV-2 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34609603/>

Case report: Pityriasis rosea-like rash after vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34557507/>

Extensive longitudinal transverse myelitis after ChAdOx1 nCoV-19 vaccine: case report: <https://pubmed.ncbi.nlm.nih.gov/34641797/>.

Acute eosinophilic pneumonia associated with anti-COVID-19 vaccine

AZD1222: <https://pubmed.ncbi.nlm.nih.gov/34812326/>.

Thrombocytopenia, including immune thrombocytopenia after receiving COVID-19 mRNA vaccines reported to the Vaccine Adverse Event Reporting System

(VAERS): <https://pubmed.ncbi.nlm.nih.gov/34006408/>

A case of ANCA-associated vasculitis after AZD1222 (Oxford-AstraZeneca) SARS-CoV-2 vaccination: victim or causality?: <https://pubmed.ncbi.nlm.nih.gov/34416184/>

Vaccine-induced immune thrombosis and thrombocytopenia syndrome after adenovirus-vectored severe acute respiratory syndrome coronavirus 2 vaccination: a new hypothesis on mechanisms and implications for future vaccine

development: <https://pubmed.ncbi.nlm.nih.gov/34664303/>.

Thrombosis in peripheral artery disease and thrombotic thrombocytopenia following adenoviral COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34649281/>.

Newly diagnosed immune thrombocytopenia in a pregnant patient after coronavirus disease 2019 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34420249/>

Cerebral venous sinus thrombosis and thrombotic events after vector-based COVID-19 vaccines: systematic review and meta-analysis: <https://pubmed.ncbi.nlm.nih.gov/34610990/>.

Sweet's syndrome after Oxford-AstraZeneca COVID-19 vaccine (AZD1222) in an elderly woman: <https://pubmed.ncbi.nlm.nih.gov/34590397/>

Sudden sensorineural hearing loss after COVID-19

vaccination: <https://pubmed.ncbi.nlm.nih.gov/34670143/>.

Prevalence of serious adverse events among health care professionals after receiving the first dose of ChAdOx1 nCoV-19 coronavirus vaccine (Covishield) in Togo, March

2021: <https://pubmed.ncbi.nlm.nih.gov/34819146/>.

Acute hemichorea-hemiballismus after COVID-19 (AZD1222)

vaccination: <https://pubmed.ncbi.nlm.nih.gov/34581453/>

Recurrence of alopecia areata after covid-19 vaccination: a report of three cases in

Italy: <https://pubmed.ncbi.nlm.nih.gov/34741583/>

Shingles-like skin lesion after vaccination with AstraZeneca for COVID-19: a case report: <https://pubmed.ncbi.nlm.nih.gov/34631069/>

Thrombosis after COVID-19 vaccination: possible link to ACE pathways: <https://pubmed.ncbi.nlm.nih.gov/34479129/>

Thrombocytopenia in an adolescent with sickle cell anemia after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34331506/>

Leukocytoclastic vasculitis as a cutaneous manifestation of ChAdOx1 corona virus vaccine nCoV-19 (recombinant): <https://pubmed.ncbi.nlm.nih.gov/34546608/>

Abdominal pain and bilateral adrenal hemorrhage from immune thrombotic thrombocytopenia induced by COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34546343/>

Longitudinally extensive cervical myelitis after vaccination with inactivated virus based COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34849183/>

Induction of cutaneous leukocytoclastic vasculitis after ChAdOx1 nCoV-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34853744/>.

A case of toxic epidermal necrolysis after vaccination with ChAdOx1 nCoV-19 (AZD1222): <https://pubmed.ncbi.nlm.nih.gov/34751429/>.

Ocular adverse events following COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34559576/>

Depression after ChAdOx1-S / nCoV-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34608345/>.

Venous thromboembolism and mild thrombocytopenia after ChAdOx1 nCoV-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34384129/>.

Recurrent ANCA-associated vasculitis after Oxford AstraZeneca ChAdOx1-S COVID-19 vaccination: a case series of two patients: <https://pubmed.ncbi.nlm.nih.gov/34755433/>

Major artery thrombosis and vaccination against ChAdOx1 nCov-19: <https://pubmed.ncbi.nlm.nih.gov/34839830/>

Rare case of contralateral supraclavicular lymphadenopathy after vaccination with COVID-19: computed tomography and ultrasound findings: <https://pubmed.ncbi.nlm.nih.gov/34667486/>

Cutaneous lymphocytic vasculitis after administration of the second dose of AZD1222 (Oxford-AstraZeneca) Severe acute respiratory syndrome Coronavirus 2 vaccine: chance or causality: <https://pubmed.ncbi.nlm.nih.gov/34726187/>.

Pancreas allograft rejection after ChAdOx1 nCoV-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34781027/>

Understanding the risk of thrombosis with thrombocytopenia syndrome following Ad26.COV2.S vaccination: <https://pubmed.ncbi.nlm.nih.gov/34595694/>

Cutaneous adverse reactions of 35,229 doses of COVID-19 Sinovac and AstraZeneca vaccine COVID-19: a prospective cohort study in health care workers: <https://pubmed.ncbi.nlm.nih.gov/34661934/>

Comments on thrombosis after vaccination: spike protein leader sequence could be responsible for thrombosis and antibody-mediated thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34788138>

Eosinophilic dermatosis after AstraZeneca COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34753210/>.

Severe immune thrombocytopenia following COVID-19 vaccination: report of four cases and review of the literature: <https://pubmed.ncbi.nlm.nih.gov/34653943/>.

Relapse of immune thrombocytopenia after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34591991/>

Thrombosis in pre- and post-vaccination phase of COVID-19; <https://pubmed.ncbi.nlm.nih.gov/34650382/>

A look at the role of postmortem immunohistochemistry in understanding the inflammatory pathophysiology of COVID-19 disease and vaccine-related thrombotic adverse events: a narrative review: <https://pubmed.ncbi.nlm.nih.gov/34769454/>

COVID-19 vaccine in patients with hypercoagulability disorders: a clinical perspective: <https://pubmed.ncbi.nlm.nih.gov/34786893/>

Vaccine-associated thrombocytopenia and thrombosis: venous endotheliopathy leading to combined venous micro-macrothrombosis: <https://pubmed.ncbi.nlm.nih.gov/34833382/>

Thrombosis and thrombocytopenia syndrome causing isolated symptomatic carotid occlusion after COVID-19 Ad26.COV2.S vaccine (Janssen): <https://pubmed.ncbi.nlm.nih.gov/34670287/>

An unusual presentation of acute deep vein thrombosis after Modern COVID-19 vaccine: case report: <https://pubmed.ncbi.nlm.nih.gov/34790811/>

Immediate high-dose intravenous immunoglobulins followed by direct treatment with thrombin inhibitors is crucial for survival in vaccine-induced immune thrombotic thrombocytopenia Sars-Covid-19-vector adenoviral VITT with venous thrombosis of the cerebral sinus and portal vein: <https://pubmed.ncbi.nlm.nih.gov/34023956/>.

Thrombosis formation after COVID-19 vaccination immunologic aspects: review article: <https://pubmed.ncbi.nlm.nih.gov/34629931/>

Imaging and hematologic findings in thrombosis and thrombocytopenia after vaccination with ChAdOx1 nCoV-19 (AstraZeneca): <https://pubmed.ncbi.nlm.nih.gov/34402666/>

Spectrum of neuroimaging findings in post-CoVID-19 vaccination: a case series and review of the literature: <https://pubmed.ncbi.nlm.nih.gov/34842783/>

Cerebral venous sinus thrombosis, pulmonary embolism, and thrombocytopenia after COVID-19 vaccination in a Taiwanese man: a case report and review of the literature: <https://pubmed.ncbi.nlm.nih.gov/34630307/>

Fatal cerebral venous sinus thrombosis after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33983464/>

Autoimmune roots of thrombotic events after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34508917/>.

New portal vein thrombosis in cirrhosis: is thrombophilia exacerbated by vaccine or COVID-19: [https://www.jcehepatology.com/article/S0973-6883\(21\)00545-4/fulltext](https://www.jcehepatology.com/article/S0973-6883(21)00545-4/fulltext).

Images of immune thrombotic thrombocytopenia induced by Oxford / AstraZeneca® COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33962903/>.

Cerebral venous sinus thrombosis after vaccination with COVID-19 mRNA of BNT162b2: <https://pubmed.ncbi.nlm.nih.gov/34796065/>.

Increased risk of urticaria/angioedema after BNT162b2 mRNA COVID-19 vaccination in health care workers taking ACE inhibitors: <https://pubmed.ncbi.nlm.nih.gov/34579248/>

A case of unusual mild clinical presentation of COVID-19 vaccine-induced immune thrombotic thrombocytopenia with splanchnic vein thrombosis: <https://pubmed.ncbi.nlm.nih.gov/34843991/>

Cerebral venous sinus thrombosis following vaccination with Pfizer-BioNTech COVID-19 (BNT162b2): <https://pubmed.ncbi.nlm.nih.gov/34595867/>

A case of idiopathic thrombocytopenic purpura after a booster dose of COVID-19 BNT162b2 vaccine (Pfizer-Biontech): <https://pubmed.ncbi.nlm.nih.gov/34820240/>

Vaccine-induced immune thrombotic immune thrombocytopenia (VITT): targeting pathologic mechanisms with Bruton's tyrosine kinase inhibitors: <https://pubmed.ncbi.nlm.nih.gov/33851389/>

Thrombotic thrombocytopenic purpura after vaccination with Ad26.COV2-S: <https://pubmed.ncbi.nlm.nih.gov/33980419/>

Thromboembolic events in younger females exposed to Pfizer-BioNTech or Moderna COVID-19 vaccines: <https://pubmed.ncbi.nlm.nih.gov/34264151/>

Potential risk of thrombotic events after COVID-19 vaccination with Oxford-AstraZeneca in women receiving estrogen: <https://pubmed.ncbi.nlm.nih.gov/34734086/>

Thrombosis after adenovirus-vectored COVID-19 vaccination: a concern for underlying disease: <https://pubmed.ncbi.nlm.nih.gov/34755555/>

Adenovirus interactions with platelets and coagulation and vaccine-induced immune thrombotic thrombocytopenia syndrome: <https://pubmed.ncbi.nlm.nih.gov/34407607/>

Thrombotic thrombocytopenic purpura: a new threat after COVID bnt162b2 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34264514/>.

Unusual site of deep vein thrombosis after vaccination against coronavirus mRNA-2019 coronavirus disease (COVID-19): <https://pubmed.ncbi.nlm.nih.gov/34840204/>

Neurological side effects of SARS-CoV-2

vaccines: <https://pubmed.ncbi.nlm.nih.gov/34750810/>

Coagulopathies after SARS-CoV-2 vaccination may derive from a combined effect of SARS-CoV-2 spike protein and adenovirus vector-activated signaling

pathways: <https://pubmed.ncbi.nlm.nih.gov/34639132/>

Isolated pulmonary embolism after COVID vaccination: 2 case reports and a review of acute pulmonary embolism complications and follow-

up: <https://pubmed.ncbi.nlm.nih.gov/34804412/>

Central retinal vein occlusion after vaccination with SARS-CoV-2 mRNA: case report: <https://pubmed.ncbi.nlm.nih.gov/34571653/>.

Complicated case report of long-term vaccine-induced thrombotic immune thrombocytopenia A: <https://pubmed.ncbi.nlm.nih.gov/34835275/>.

Deep venous thrombosis after vaccination with Ad26.COV2.S in adult males: <https://pubmed.ncbi.nlm.nih.gov/34659839/>.

Neurological autoimmune diseases after SARS-CoV-2 vaccination: a case series: <https://pubmed.ncbi.nlm.nih.gov/34668274/>.

Severe autoimmune hemolytic autoimmune anemia after receiving SARS-CoV-2 mRNA vaccine: <https://pubmed.ncbi.nlm.nih.gov/34549821/>

Occurrence of COVID-19 variants among recipients of ChAdOx1 nCoV-19 vaccine (recombinant): <https://pubmed.ncbi.nlm.nih.gov/34528522/>

Prevalence of thrombocytopenia, anti-platelet factor 4 antibodies, and elevated D-dimer in Thais after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34568726/>

Epidemiology of acute myocarditis/pericarditis in Hong Kong adolescents after co-vaccination: <https://academic.oup.com/cid/advance-article-abstract/doi/10.1093/cid/ciab989/6445179>.

Myocarditis after 2019 coronavirus disease mRNA vaccine: a case series and determination of incidence rate: <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab926/6420408>

Myocarditis and pericarditis after COVID-19 vaccination: inequalities in age and vaccine types: <https://www.mdpi.com/2075-4426/11/11/1106>

Epidemiology and clinical features of myocarditis/pericarditis before the introduction of COVID-19 mRNA vaccine in Korean children: a multicenter study: <https://pubmed.ncbi.nlm.nih.gov/34402230/>

Shedding light on post-vaccination myocarditis and pericarditis in COVID-19 and non-COVID-19 vaccine recipients: <https://pubmed.ncbi.nlm.nih.gov/34696294/>

Myocarditis Following mRNA COVID-19 Vaccine: https://journals.lww.com/pec-online/Abstract/2021/11000/Myocarditis_Following_mRNA_COVID_19_Vaccine.9.aspx.

Myocarditis following BNT162b2 mRNA Covid-19 mRNA vaccine in Israel: <https://pubmed.ncbi.nlm.nih.gov/34614328/>.

Myocarditis, pericarditis, and cardiomyopathy following COVID-19 vaccination: [https://www.heartlungcirc.org/article/S1443-9506\(21\)01156-2/fulltext](https://www.heartlungcirc.org/article/S1443-9506(21)01156-2/fulltext)

Myocarditis and other cardiovascular complications of COVID-19 mRNA-based COVID-19 vaccines: <https://pubmed.ncbi.nlm.nih.gov/34277198/>

Possible Association Between COVID-19 Vaccine and Myocarditis: Clinical and CMR Findings: <https://pubmed.ncbi.nlm.nih.gov/34246586/>

Hypersensitivity Myocarditis and COVID-19 Vaccines: <https://pubmed.ncbi.nlm.nih.gov/34856634/>.

Severe myocarditis associated with COVID-19 vaccine: zebra or unicorn?: [https://www.internationaljournalofcardiology.com/article/S0167-5273\(21\)01477-7/fulltext](https://www.internationaljournalofcardiology.com/article/S0167-5273(21)01477-7/fulltext).

Acute myocardial infarction and myocarditis after COVID-19 vaccination: <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8522388/>

Myocarditis after Covid-19 vaccination in a large healthcare organization: <https://www.nejm.org/doi/10.1056/NEJMoa2110737>

Association of myocarditis with COVID-19 messenger RNA BNT162b2 vaccine in a case series of children: <https://jamanetwork.com/journals/jamacardiology/fullarticle/2783052>

Clinical suspicion of myocarditis temporally related to COVID-19 vaccination in adolescents and young

adults: https://www.ahajournals.org/doi/abs/10.1161/CIRCULATIONAHA.121.056583?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed

STEMI mimicry: focal myocarditis in an adolescent patient after COVID-19 mRNA vaccination.: <https://pubmed.ncbi.nlm.nih.gov/34756746/>

Myocarditis and pericarditis in association with COVID-19 mRNA vaccination: cases from a regional pharmacovigilance

center: <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8587334/>

Myocarditis after COVID-19 mRNA vaccines: <https://pubmed.ncbi.nlm.nih.gov/34546329/>.

Patients with acute myocarditis after COVID-19 mRNA

vaccination.: <https://jamanetwork.com/journals/jamacardiology/fullarticle/2781602>.

Myocarditis after COVID-19 vaccination: a case

series: <https://www.sciencedirect.com/science/article/pii/S0264410X21011725?via%3Dihub>

Myocarditis associated with COVID-19 vaccination in

adolescents: <https://publications.aap.org/pediatrics/article/148/5/e2021053427/181357>

Myocarditis findings on cardiac magnetic resonance imaging after vaccination with COVID-

19 mRNA in adolescents.: <https://pubmed.ncbi.nlm.nih.gov/34704459/>

Myocarditis after COVID-19 vaccination: magnetic resonance imaging

study: <https://academic.oup.com/ehjcmimaging/advance-article/doi/10.1093/ehjci/jeab230/6421640>.

Acute myocarditis after administration of the second dose of BNT162b2 COVID-19

vaccine: <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8599115/>

Myocarditis after COVID-19

vaccination: <https://www.sciencedirect.com/science/article/pii/S2352906721001603>

Case report: probable myocarditis after Covid-19 mRNA vaccine in a patient with arrhythmogenic left ventricular

cardiomyopathy: <https://pubmed.ncbi.nlm.nih.gov/34712717/>.

Acute myocarditis after administration of BNT162b2 vaccine against COVID-19: <https://www.revespcardiol.org/en-linkresolver-acute-myocarditis-after-administration-bnt162b2-S188558572100133X>.

Myocarditis associated with COVID-19 mRNA vaccination: <https://pubs.rsna.org/doi/10.1148/radiol.2021211430>

Acute myocarditis after COVID-19 vaccination: a case report: <https://www.sciencedirect.com/science/article/pii/S0248866321007098>

Acute myopericarditis after COVID-19 vaccination in adolescents: <https://pubmed.ncbi.nlm.nih.gov/34589238/>.

Perimyocarditis in adolescents after Pfizer-BioNTech COVID-19 vaccination: <https://academic.oup.com/jpids/article/10/10/962/6329543>.

Acute myocarditis associated with anti-COVID-19 vaccination: <https://ecevr.org/DOIx.php?id=10.7774/cevr.2021.10.2.196>.

Myocarditis associated with COVID-19 vaccination: echocardiographic, cardiac CT, and MRI findings: <https://pubmed.ncbi.nlm.nih.gov/34428917/>.

Acute symptomatic myocarditis in 7 adolescents after Pfizer-BioNTech COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34088762/>.

Myocarditis and pericarditis in adolescents after first and second doses of COVID-19 mRNA vaccines: <https://academic.oup.com/ehjqcco/advance-article/doi/10.1093/ehjqcco/qcab090/6442104>.

COVID 19 vaccine for adolescents. Concern for myocarditis and pericarditis: <https://www.mdpi.com/2036-7503/13/3/61>.

Cardiac imaging of acute myocarditis after vaccination with COVID-19 mRNA: <https://pubmed.ncbi.nlm.nih.gov/34402228/>

Myocarditis temporally associated with COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34133885/>

Acute myocardial injury after COVID-19 vaccination: a case report and review of current evidence from the vaccine adverse event reporting system database: <https://pubmed.ncbi.nlm.nih.gov/34219532/>

Acute myocarditis associated with COVID-19 vaccination: report of a case: <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8639400/>

Myocarditis following vaccination with COVID-19 messenger RNA: a Japanese case series: <https://pubmed.ncbi.nlm.nih.gov/34840235/>.

Myocarditis in the setting of a recent COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34712497/>.

Acute myocarditis after a second dose of COVID-19 mRNA vaccine: report of two cases: [https://www.clinicalimaging.org/article/S0899-7071\(21\)00265-5/fulltext](https://www.clinicalimaging.org/article/S0899-7071(21)00265-5/fulltext).

Prevalence of thrombocytopenia, antiplatelet factor 4 antibodies, and elevated D-dimer in Thais after vaccination with ChAdOx1 nCoV-19: <https://pubmed.ncbi.nlm.nih.gov/34568726/>

Epidemiology of acute myocarditis/pericarditis in Hong Kong adolescents after co-vaccination: <https://academic.oup.com/cid/advance-article-abstract/doi/10.1093/cid/ciab989/6445179>

Myocarditis after 2019 coronavirus disease mRNA vaccine: a case series and incidence rate determination: <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab926/6420408>.

Myocarditis and pericarditis after COVID-19 vaccination: inequalities in age and vaccine types: <https://www.mdpi.com/2075-4426/11/11/1106>

Epidemiology and clinical features of myocarditis/pericarditis before the introduction of COVID-19 mRNA vaccine in Korean children: a multicenter study: <https://pubmed.ncbi.nlm.nih.gov/34402230/>

Shedding light on post-vaccination myocarditis and pericarditis in COVID-19 and non-COVID-19 vaccine recipients: <https://pubmed.ncbi.nlm.nih.gov/34696294/>

Diffuse prothrombotic syndrome after administration of ChAdOx1 nCoV-19 vaccine: case report: <https://pubmed.ncbi.nlm.nih.gov/34615534/>

Three cases of acute venous thromboembolism in women after coronavirus 2019 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34352418/>

Clinical and biological features of cerebral venous sinus thrombosis after vaccination with ChAdOx1 nCov-19; <https://jnnp.bmj.com/content/early/2021/09/29/jnnp-2021-327340>.

CAd26.COV2-S vaccination may reveal hereditary thrombophilia: massive cerebral venous sinus thrombosis in a young man with normal platelet count: <https://pubmed.ncbi.nlm.nih.gov/34632750/>

Post-mortem findings in vaccine-induced thrombotic thrombocytopenia: <https://haematologica.org/article/view/haematol.2021.279075>

COVID-19 vaccine-induced thrombosis: <https://pubmed.ncbi.nlm.nih.gov/34802488/>.

Inflammation and platelet activation after COVID-19 vaccines: possible mechanisms behind vaccine-induced immune thrombocytopenia and thrombosis: <https://pubmed.ncbi.nlm.nih.gov/34887867/>.

Anaphylactoid reaction and coronary thrombosis related to COVID-19 mRNA vaccine: <https://pubmed.ncbi.nlm.nih.gov/34863404/>.

Vaccine-induced cerebral venous thrombosis and thrombocytopenia. Oxford-AstraZeneca COVID-19: a missed opportunity for rapid return on experience: <https://www.sciencedirect.com/science/article/pii/S235255682100093X>

Occurrence of splenic infarction due to arterial thrombosis after vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34876440/>

Deep venous thrombosis more than two weeks after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33928773/>

Case report: Take a second look: Cerebral venous thrombosis related to Covid-19 vaccination and thrombotic thrombocytopenia syndrome: <https://pubmed.ncbi.nlm.nih.gov/34880826/>

Information on ChAdOx1 nCoV-19 vaccine-induced immune-mediated thrombotic thrombocytopenia: <https://pubmed.ncbi.nlm.nih.gov/34587242/>

Change in blood viscosity after COVID-19 vaccination: estimation for persons with underlying metabolic syndrome: <https://pubmed.ncbi.nlm.nih.gov/34868465/>

Management of a patient with a rare congenital limb malformation syndrome after SARS-CoV-2 vaccine-induced thrombosis and thrombocytopenia (VITT): <https://pubmed.ncbi.nlm.nih.gov/34097311/>

Bilateral thalamic stroke: a case of COVID-19 (VITT) vaccine-induced immune thrombotic thrombocytopenia or a coincidence due to underlying risk factors: <https://pubmed.ncbi.nlm.nih.gov/34820232/>.

Thrombocytopenia and splanchnic thrombosis after vaccination with Ad26.COV2.S successfully treated with transjugular intrahepatic intrahepatic portosystemic shunt and thrombectomy: <https://onlinelibrary.wiley.com/doi/10.1002/ajh.26258>

Incidence of acute ischemic stroke after coronavirus vaccination in Indonesia: case series: <https://pubmed.ncbi.nlm.nih.gov/34579636/>

Successful treatment of vaccine-induced immune immune thrombotic thrombocytopenia in a 26-year-old female patient: <https://pubmed.ncbi.nlm.nih.gov/34614491/>

Case report: vaccine-induced immune immune thrombotic thrombocytopenia in a patient with pancreatic cancer after vaccination with messenger RNA-1273: <https://pubmed.ncbi.nlm.nih.gov/34790684/>

Idiopathic idiopathic external jugular vein thrombophlebitis after coronavirus disease vaccination (COVID-19): <https://pubmed.ncbi.nlm.nih.gov/33624509/>.

Squamous cell carcinoma of the lung with hemoptysis following vaccination with tozinameran (BNT162b2, Pfizer-BioNTech): <https://pubmed.ncbi.nlm.nih.gov/34612003/>

Vaccine-induced thrombotic thrombocytopenia after Ad26.COV2.S vaccination in a man presenting as acute venous thromboembolism: <https://pubmed.ncbi.nlm.nih.gov/34096082/>

Myocarditis associated with COVID-19 vaccination in three adolescent boys: <https://pubmed.ncbi.nlm.nih.gov/34851078/>.

Cardiovascular magnetic resonance findings in young adult patients with acute myocarditis after COVID-19 mRNA vaccination: a case series: <https://pubmed.ncbi.nlm.nih.gov/34496880/>

Perimyocarditis after vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34866957/>

Epidemiology of acute myocarditis/pericarditis in Hong Kong adolescents after co-vaccination: <https://pubmed.ncbi.nlm.nih.gov/34849657/>.

Myocarditis-induced sudden death after BNT162b2 COVID-19 mRNA vaccination in Korea: case report focusing on histopathological findings: <https://pubmed.ncbi.nlm.nih.gov/34664804/>

Acute myocarditis after vaccination with COVID-19 mRNA in adults aged 18 years or older: <https://pubmed.ncbi.nlm.nih.gov/34605853/>

Recurrence of acute myocarditis temporally associated with receipt of the 2019 coronavirus mRNA disease vaccine (COVID-19) in an adolescent male: <https://pubmed.ncbi.nlm.nih.gov/34166671/>

Young male with myocarditis after mRNA-1273 coronavirus disease-2019 (COVID-19) mRNA vaccination: <https://pubmed.ncbi.nlm.nih.gov/34744118/>

Acute myocarditis after SARS-CoV-2 vaccination in a 24-year-old male: <https://pubmed.ncbi.nlm.nih.gov/34334935/>.

Ga-DOTATOC digital PET images of inflammatory cell infiltrates in myocarditis after vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34746968/>

Occurrence of acute infarct-like myocarditis after vaccination with COVID-19: just an accidental coincidence or rather a vaccination-associated autoimmune myocarditis?": <https://pubmed.ncbi.nlm.nih.gov/34333695/>.

Self-limited myocarditis presenting with chest pain and ST-segment elevation in adolescents after vaccination with BNT162b2 mRNA vaccine: <https://pubmed.ncbi.nlm.nih.gov/34180390/>

Myocarditis Following Immunization with COVID-19 mRNA Vaccines in Members of the U.S. Military: <https://pubmed.ncbi.nlm.nih.gov/34185045/>

Myocarditis after BNT162b2 vaccination in a healthy male: <https://pubmed.ncbi.nlm.nih.gov/34229940/>

Myopericarditis in a previously healthy adolescent male after COVID-19 vaccination: Case report: <https://pubmed.ncbi.nlm.nih.gov/34133825/>

Acute myocarditis after SARS-CoV-2 mRNA-1273 mRNA vaccination: <https://pubmed.ncbi.nlm.nih.gov/34308326/>.

Chest pain with abnormal electrocardiogram redevelopment after injection of COVID-19 vaccine manufactured by Moderna: <https://pubmed.ncbi.nlm.nih.gov/34866106/>

Biopsy-proven lymphocytic myocarditis after first vaccination with COVID-19 mRNA in a 40-year-old man: case report: <https://pubmed.ncbi.nlm.nih.gov/34487236/>

Multimodality imaging and histopathology in a young man presenting with fulminant lymphocytic myocarditis and cardiogenic shock after vaccination with mRNA-1273: <https://pubmed.ncbi.nlm.nih.gov/34848416/>

Report of a case of myopericarditis after vaccination with BNT162b2 COVID-19 mRNA in a young Korean male: <https://pubmed.ncbi.nlm.nih.gov/34636504/>

Acute myocarditis after Comirnaty vaccination in a healthy male with previous SARS-CoV-2 infection: <https://pubmed.ncbi.nlm.nih.gov/34367386/>

Acute myocarditis in a young adult two days after vaccination with Pfizer: <https://pubmed.ncbi.nlm.nih.gov/34709227/>

Case report: acute fulminant myocarditis and cardiogenic shock after messenger RNA coronavirus vaccination in 2019 requiring extracorporeal cardiopulmonary resuscitation: <https://pubmed.ncbi.nlm.nih.gov/34778411/>

Acute myocarditis after 2019 coronavirus disease vaccination: <https://pubmed.ncbi.nlm.nih.gov/34734821/>

A series of patients with myocarditis after vaccination against SARS-CoV-2 with mRNA-1279 and BNT162b2: <https://pubmed.ncbi.nlm.nih.gov/34246585/>

Myopericarditis after Pfizer messenger ribonucleic acid coronavirus disease vaccine in adolescents: <https://pubmed.ncbi.nlm.nih.gov/34228985/>

Post-vaccination multisystem inflammatory syndrome in adults without evidence of prior SARS-CoV-2 infection: <https://pubmed.ncbi.nlm.nih.gov/34852213/>

Acute myocarditis defined after vaccination with 2019 mRNA of coronavirus disease: <https://pubmed.ncbi.nlm.nih.gov/34866122/>

Biventricular systolic dysfunction in acute myocarditis after SARS-CoV-2 mRNA-1273 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34601566/>

Myocarditis following COVID-19 vaccination: MRI study: <https://pubmed.ncbi.nlm.nih.gov/34739045/>.

Acute myocarditis after COVID-19 vaccination: case report: https://docs.google.com/document/d/1Hc4bh_qNbZ7UVm5BLxkRdMPnnI9zcCsl/e

Association of myocarditis with COVID-19 messenger RNA BNT162b2 vaccine COVID-19 in a case series of children: <https://pubmed.ncbi.nlm.nih.gov/34374740/>

Clinical suspicion of myocarditis temporally related to COVID-19 vaccination in adolescents and young adults: <https://pubmed.ncbi.nlm.nih.gov/34865500/>

Myocarditis following vaccination with Covid-19 in a large healthcare organization: <https://pubmed.ncbi.nlm.nih.gov/34614329/>

AstraZeneca COVID-19 vaccine and Guillain-Barré syndrome in Tasmania: a causal link: <https://pubmed.ncbi.nlm.nih.gov/34560365/>

COVID-19, Guillain-Barré and vaccineA dangerous mix: <https://pubmed.ncbi.nlm.nih.gov/34108736/>.

Guillain-Barré syndrome after the first dose of Pfizer-BioNTech COVID-19 vaccine: case report and review of reported cases: <https://pubmed.ncbi.nlm.nih.gov/34796417/>.

Guillain-Barre syndrome after BNT162b2 COVID-19 vaccine: <https://link.springer.com/article/10.1007%2Fs10072-021-05523-5>.

COVID-19 adenovirus vaccines and Guillain-Barré syndrome with facial palsy: <https://onlinelibrary.wiley.com/doi/10.1002/ana.26258>.

Association of receipt association of Ad26.COV2.S COVID-19 vaccine with presumed Guillain-Barre syndrome, February-July 2021: <https://jamanetwork.com/journals/jama/fullarticle/2785009>

A case of Guillain-Barré syndrome after Pfizer COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34567447/>

Guillain-Barré syndrome associated with COVID-19
vaccination: <https://pubmed.ncbi.nlm.nih.gov/34648420/>.

Rate of recurrent Guillain-Barré syndrome after COVID-19 BNT162b2 mRNA
vaccine: <https://jamanetwork.com/journals/jamaneurology/fullarticle/2783708>

Guillain-Barre syndrome after COVID-19 vaccination in an
adolescent: [https://www.pedneur.com/article/S0887-8994\(21\)00221-6/fulltext](https://www.pedneur.com/article/S0887-8994(21)00221-6/fulltext).

Guillain-Barre syndrome after ChAdOx1-S / nCoV-19
vaccination: <https://pubmed.ncbi.nlm.nih.gov/34114256/>.

Guillain-Barre syndrome after COVID-19 mRNA-1273 vaccine: case
report: <https://pubmed.ncbi.nlm.nih.gov/34767184/>.

Guillain-Barre syndrome following SARS-CoV-2 vaccination in 19
patients: <https://pubmed.ncbi.nlm.nih.gov/34644738/>.

Guillain-Barre syndrome presenting with facial diplegia following vaccination with COVID-
19 in two patients: <https://pubmed.ncbi.nlm.nih.gov/34649856/>

A rare case of Guillain-Barré syndrome after COVID-19
vaccination: <https://pubmed.ncbi.nlm.nih.gov/34671572/>

Neurological complications of COVID-19: Guillain-Barre syndrome after Pfizer COVID-19
vaccine: <https://pubmed.ncbi.nlm.nih.gov/33758714/>

COVID-19 vaccine causing Guillain-Barre syndrome, an uncommon potential side
effect: <https://pubmed.ncbi.nlm.nih.gov/34484780/>

Guillain-Barre syndrome after the first dose of COVID-19 vaccination: case
report; <https://pubmed.ncbi.nlm.nih.gov/34779385/>.

Miller Fisher syndrome after Pfizer COVID-19
vaccine: <https://pubmed.ncbi.nlm.nih.gov/34817727/>.

Miller Fisher syndrome after 2019 BNT162b2 mRNA coronavirus
vaccination: <https://pubmed.ncbi.nlm.nih.gov/34789193/>.

Bilateral facial weakness with a variant of paresthesia of Guillain-Barre syndrome after
Vaxzevria COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34261746/>

Guillain-Barre syndrome after the first injection of ChAdOx1 nCoV-19 vaccine: first report: <https://pubmed.ncbi.nlm.nih.gov/34217513/>.

A case of sensory ataxic Guillain-Barre syndrome with immunoglobulin G anti-GM1 antibodies after first dose of COVID-19 BNT162b2 mRNA vaccine (Pfizer): <https://pubmed.ncbi.nlm.nih.gov/34871447/>

Reporting of acute inflammatory neuropathies with COVID-19 vaccines: subgroup disproportionality analysis in Vigibase: <https://pubmed.ncbi.nlm.nih.gov/34579259/>

A variant of Guillain-Barré syndrome after SARS-CoV-2 vaccination: AMSAN: <https://pubmed.ncbi.nlm.nih.gov/34370408/>.

A rare variant of Guillain-Barré syndrome after vaccination with Ad26.COV2.S: <https://pubmed.ncbi.nlm.nih.gov/34703690/>.

Guillain-Barré syndrome after SARS-CoV-2 vaccination in a patient with previous vaccine-associated Guillain-Barré syndrome: <https://pubmed.ncbi.nlm.nih.gov/34810163/>

Guillain-Barré syndrome in an Australian state using mRNA and adenovirus-vector SARS-CoV-2 vaccines: <https://onlinelibrary.wiley.com/doi/10.1002/ana.26218>.

Acute transverse myelitis after SARS-CoV-2 vaccination: case report and review of the literature: <https://pubmed.ncbi.nlm.nih.gov/34482455/>.

Variant Guillain-Barré syndrome occurring after SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34114269/>.

Guillain-Barre syndrome with axonal variant temporally associated with Modern SARS-CoV-2 mRNA-based vaccine: <https://pubmed.ncbi.nlm.nih.gov/34722067/>

Guillain-Barre syndrome after the first dose of SARS-CoV-2 vaccine: a temporary occurrence, not a causal association: <https://pubmed.ncbi.nlm.nih.gov/33968610/>

SARS-CoV-2 vaccines can be complicated not only by Guillain-Barré syndrome but also by distal small fiber neuropathy: <https://pubmed.ncbi.nlm.nih.gov/34525410/>

Clinical variant of Guillain-Barré syndrome with prominent facial diplegia after AstraZeneca 2019 coronavirus disease vaccine: <https://pubmed.ncbi.nlm.nih.gov/34808658/>

Adverse event reporting and risk of Bell's palsy after COVID-19

vaccination: [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(21\)00646-0/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00646-0/fulltext).

Bilateral facial nerve palsy and COVID-19 vaccination: causality or

coincidence: <https://pubmed.ncbi.nlm.nih.gov/34522557/>

Left Bell's palsy after the first dose of mRNA-1273 SARS-CoV-2 vaccine: case

report: <https://pubmed.ncbi.nlm.nih.gov/34763263/>.

Bell's palsy after inactivated vaccination with COVID-19 in a patient with a history of

recurrent Bell's palsy: case report: <https://pubmed.ncbi.nlm.nih.gov/34621891/>

Neurological complications after the first dose of COVID-19 vaccines and SARS-CoV-2

infection: <https://pubmed.ncbi.nlm.nih.gov/34697502/>

Type I interferons as a potential mechanism linking COVID-19 mRNA vaccines with Bell's

palsy: <https://pubmed.ncbi.nlm.nih.gov/33858693/>

Acute transverse myelitis following inactivated COVID-19

vaccine: <https://pubmed.ncbi.nlm.nih.gov/34370410/>

Acute transverse myelitis after COVID-19

vaccination: <https://pubmed.ncbi.nlm.nih.gov/34579245/>.

A case of longitudinally extensive transverse myelitis following Covid-19

vaccination: <https://pubmed.ncbi.nlm.nih.gov/34182207/>

Post COVID-19 transverse myelitis; a case report with review of the

literature: <https://pubmed.ncbi.nlm.nih.gov/34457267/>.

Beware of neuromyelitis optica spectrum disorder after vaccination with inactivated virus

for COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34189662/>

Neuromyelitis optica in a healthy woman after vaccination against severe acute respiratory

syndrome coronavirus 2 mRNA-1273: <https://pubmed.ncbi.nlm.nih.gov/34660149/>

Acute bilateral bilateral optic neuritis/chiasm with longitudinal extensive transverse myelitis

in long-standing stable multiple sclerosis after vector-based vaccination against SARS-CoV-

2: <https://pubmed.ncbi.nlm.nih.gov/34131771/>

A case series of acute pericarditis after vaccination with COVID-19 in the context of recent reports from Europe and the United States: <https://pubmed.ncbi.nlm.nih.gov/34635376/>

Acute pericarditis and cardiac tamponade after vaccination with Covid-19: <https://pubmed.ncbi.nlm.nih.gov/34749492/>

Myocarditis and pericarditis in adolescents after the first and second doses of COVID-19 mRNA vaccines: <https://pubmed.ncbi.nlm.nih.gov/34849667/>

Perimyocarditis in adolescents after Pfizer-BioNTech COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34319393/>

Acute myopericarditis after COVID-19 vaccine in adolescents: <https://pubmed.ncbi.nlm.nih.gov/34589238/>

Pericarditis after administration of the BNT162b2 mRNA vaccine COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34149145/>

Case report: symptomatic pericarditis post COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34693198/>.

An outbreak of Still's disease after COVID-19 vaccination in a 34-year-old patient: <https://pubmed.ncbi.nlm.nih.gov/34797392/>

Hemophagocytic lymphohistiocytosis following COVID-19 vaccination (ChAdOx1 nCoV-19): <https://pubmed.ncbi.nlm.nih.gov/34862234/>

Myocarditis after SARS-CoV-2 mRNA vaccination, a case series: <https://pubmed.ncbi.nlm.nih.gov/34396358/>.

Miller-Fisher syndrome and Guillain-Barré syndrome overlap syndrome in a patient after Oxford-AstraZeneca SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34848426/>.

Immune-mediated disease outbreaks or new-onset disease in 27 subjects after mRNA/DNA vaccination against SARS-CoV-2: <https://pubmed.ncbi.nlm.nih.gov/33946748/>

Post-mortem investigation of deaths after vaccination with COVID-19 vaccines: <https://pubmed.ncbi.nlm.nih.gov/34591186/>

Acute kidney injury with macroscopic hematuria and IgA nephropathy after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34352309/>

Relapse of immune thrombocytopenia after covid-19 vaccination in young male patient: <https://pubmed.ncbi.nlm.nih.gov/34804803/>.

Immune thrombocytopenic purpura associated with COVID-19 mRNA vaccine Pfizer-BioNTech BNT16B2b2: <https://pubmed.ncbi.nlm.nih.gov/34077572/>

Retinal hemorrhage after SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34884407/>.

Case report: anti-neutrophil cytoplasmic antibody-associated vasculitis with acute renal failure and pulmonary hemorrhage can occur after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34859017/>

Intracerebral hemorrhage due to vasculitis following COVID-19 vaccination: case report: <https://pubmed.ncbi.nlm.nih.gov/34783899/>

Peduncular, symptomatic cavernous bleeding after immune thrombocytopenia-induced SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34549178/>.

Brain death in a vaccinated patient with COVID-19 infection: <https://pubmed.ncbi.nlm.nih.gov/34656887/>

Generalized purpura annularis telangiectodes after SARS-CoV-2 mRNA vaccination: <https://pubmed.ncbi.nlm.nih.gov/34236717/>.

Lobar hemorrhage with ventricular rupture shortly after the first dose of a SARS-CoV-2 mRNA-based SARS-CoV-2 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34729467/>.

A case of outbreak of macroscopic hematuria and IgA nephropathy after SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33932458/>

Acral hemorrhage after administration of the second dose of SARS-CoV-2 vaccine. A post-vaccination reaction: <https://pubmed.ncbi.nlm.nih.gov/34092400/742>.

Severe immune thrombocytopenic purpura after SARS-CoV-2 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34754937/>

Gross hematuria after severe acute respiratory syndrome coronavirus 2 vaccination in 2 patients with IgA nephropathy: <https://pubmed.ncbi.nlm.nih.gov/33771584/>

Autoimmune encephalitis after ChAdOx1-S SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34846583/>

COVID-19 vaccine and death: causality algorithm according to the WHO eligibility diagnosis: <https://pubmed.ncbi.nlm.nih.gov/34073536/>

Bell's palsy after vaccination with mRNA (BNT162b2) and inactivated (CoronaVac) SARS-CoV-2 vaccines: a case series and a nested case-control study: <https://pubmed.ncbi.nlm.nih.gov/34411532/>

Epidemiology of myocarditis and pericarditis following mRNA vaccines in Ontario, Canada: by vaccine product, schedule, and interval: <https://www.medrxiv.org/content/10.1101/2021.12.02.21267156v1>

Anaphylaxis following Covid-19 vaccine in a patient with cholinergic urticaria: <https://pubmed.ncbi.nlm.nih.gov/33851711/>

Anaphylaxis induced by CoronaVac COVID-19 vaccine: clinical features and results of revaccination: <https://pubmed.ncbi.nlm.nih.gov/34675550/>.

Anaphylaxis after Modern COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34734159/>.

Association of self-reported history of high-risk allergy with allergy symptoms after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34698847/>

Sex differences in the incidence of anaphylaxis to LNP-mRNA vaccines COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34020815/>

Allergic reactions, including anaphylaxis, after receiving the first dose of Pfizer-BioNTech COVID-19 vaccine – United States, December 14 to 23, 2020: <https://pubmed.ncbi.nlm.nih.gov/33641264/>

Allergic reactions, including anaphylaxis, after receiving the first dose of Modern COVID-19 vaccine – United States, December 21, 2020 to January 10, 2021: <https://pubmed.ncbi.nlm.nih.gov/33641268/>

Prolonged anaphylaxis to Pfizer 2019 coronavirus disease vaccine: a case report and mechanism of action: <https://pubmed.ncbi.nlm.nih.gov/33834172/>

Anaphylaxis reactions to Pfizer BNT162b2 vaccine: report of 3 cases of anaphylaxis following vaccination with Pfizer BNT162b2: <https://pubmed.ncbi.nlm.nih.gov/34579211/>

Biphasic anaphylaxis after first dose of 2019 messenger RNA coronavirus disease vaccine with positive polysorbate 80 skin test result: <https://pubmed.ncbi.nlm.nih.gov/34343674/>

Acute myocardial infarction and myocarditis after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34586408/>

Takotsubo syndrome after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34539938/>.

Takotsubo cardiomyopathy after coronavirus 2019 vaccination in patient on maintenance hemodialysis: <https://pubmed.ncbi.nlm.nih.gov/34731486/>.

Premature myocardial infarction or side effect of COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33824804/>

Myocardial infarction, stroke, and pulmonary embolism after BNT162b2 mRNA COVID-19 vaccine in persons aged 75 years or older: <https://pubmed.ncbi.nlm.nih.gov/34807248/>

Kounis syndrome type 1 induced by inactivated SARS-CoV-2 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34148772/>

Acute myocardial infarction within 24 hours after COVID-19 vaccination: is Kounis syndrome the culprit: <https://pubmed.ncbi.nlm.nih.gov/34702550/>

Deaths associated with the recently launched SARS-CoV-2 vaccination (Comirnaty®): <https://pubmed.ncbi.nlm.nih.gov/33895650/>

Deaths associated with recently launched SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34425384/>

A case of acute encephalopathy and non-ST-segment elevation myocardial infarction after vaccination with mRNA-1273: possible adverse effect: <https://pubmed.ncbi.nlm.nih.gov/34703815/>

COVID-19 vaccine-induced urticarial vasculitis: <https://pubmed.ncbi.nlm.nih.gov/34369046/>.

ANCA-associated vasculitis after Pfizer-BioNTech COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34280507/>.

New-onset leukocytoclastic vasculitis after COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34241833/>

Cutaneous small vessel vasculitis after COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34529877/>.

Outbreak of leukocytoclastic vasculitis after COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33928638/>

Leukocytoclastic vasculitis after exposure to COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34836739/>

Vasculitis and bursitis in [18 F] FDG-PET/CT after COVID-19 mRNA vaccine: post hoc ergo propter hoc?; <https://pubmed.ncbi.nlm.nih.gov/34495381/>.

Cutaneous lymphocytic vasculitis after administration of COVID-19 mRNA vaccine: <https://pubmed.ncbi.nlm.nih.gov/34327795>

Cutaneous leukocytoclastic vasculitis induced by Sinovac COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34660867/>.

Case report: ANCA-associated vasculitis presenting with rhabdomyolysis and crescentic Pauci-Immune glomerulonephritis after vaccination with Pfizer-BioNTech COVID-19 mRNA: <https://pubmed.ncbi.nlm.nih.gov/34659268/>

Reactivation of IgA vasculitis after vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34848431/>

Varicella-zoster virus-related small-vessel vasculitis after Pfizer-BioNTech COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34310759/>.

Imaging in vascular medicine: leukocytoclastic vasculitis after COVID-19 vaccine booster: <https://pubmed.ncbi.nlm.nih.gov/34720009/>

A rare case of Henoch-Schönlein purpura after a case report of COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34518812/>

Cutaneous vasculitis following COVID-19

vaccination: <https://pubmed.ncbi.nlm.nih.gov/34611627/>.

Possible case of COVID-19 mRNA vaccine-induced small-vessel

vasculitis: <https://pubmed.ncbi.nlm.nih.gov/34705320/>.

IgA vasculitis following COVID-19 vaccination in an

adult: <https://pubmed.ncbi.nlm.nih.gov/34779011/>

Propylthiouracil-induced anti-neutrophil cytoplasmic antibody-associated vasculitis

following vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34451967/>

Coronavirus disease vaccine 2019 (COVID-19) in systemic lupus erythematosus and neutrophil anti-cytoplasmic antibody-associated

vasculitis: <https://pubmed.ncbi.nlm.nih.gov/33928459/>

Reactivation of IgA vasculitis after COVID-19

vaccination: <https://pubmed.ncbi.nlm.nih.gov/34250509/>

Clinical and histopathologic spectrum of delayed adverse skin reactions after COVID-19

vaccination: <https://pubmed.ncbi.nlm.nih.gov/34292611/>.

First description of immune complex vasculitis after COVID-19 vaccination with

BNT162b2: case report: <https://pubmed.ncbi.nlm.nih.gov/34530771/>.

Nephrotic syndrome and vasculitis after SARS-CoV-2 vaccine: true association or

circumstantial: <https://pubmed.ncbi.nlm.nih.gov/34245294/>.

Occurrence of de novo cutaneous vasculitis after vaccination against coronavirus disease

(COVID-19): <https://pubmed.ncbi.nlm.nih.gov/34599716/>.

Asymmetric cutaneous vasculitis after COVID-19 vaccination with unusual preponderance of eosinophils: <https://pubmed.ncbi.nlm.nih.gov/34115904/>.

Henoch-Schönlein purpura occurring after vaccination with COVID-

19: <https://pubmed.ncbi.nlm.nih.gov/34247902/>.

Henoch-Schönlein purpura following the first dose of COVID-19 viral vector vaccine: case

report: <https://pubmed.ncbi.nlm.nih.gov/34696186/>.

Granulomatous vasculitis after AstraZeneca anti-SARS-CoV-2

vaccine: <https://pubmed.ncbi.nlm.nih.gov/34237323/>.

Acute retinal necrosis due to varicella zoster virus reactivation after vaccination with BNT162b2 COVID-19 mRNA: <https://pubmed.ncbi.nlm.nih.gov/34851795/>.

A case of generalized Sweet's syndrome with vasculitis triggered by recent vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34849386/>

Small-vessel vasculitis following Oxford-AstraZeneca vaccination against SARS-CoV-2: <https://pubmed.ncbi.nlm.nih.gov/34310763/>

Relapse of microscopic polyangiitis after COVID-19 vaccination: case report: <https://pubmed.ncbi.nlm.nih.gov/34251683/>.

Cutaneous vasculitis after severe acute respiratory syndrome coronavirus 2 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34557622/>.

Recurrent herpes zoster after COVID-19 vaccination in patients with chronic urticaria on cyclosporine treatment – A report of 3 cases: <https://pubmed.ncbi.nlm.nih.gov/34510694/>

Leukocytoclastic vasculitis after coronavirus disease vaccination 2019: <https://pubmed.ncbi.nlm.nih.gov/34713472/803>

Outbreaks of mixed cryoglobulinemia vasculitis after vaccination against SARS-CoV-2: <https://pubmed.ncbi.nlm.nih.gov/34819272/>

Cutaneous small-vessel vasculitis after vaccination with a single dose of Janssen Ad26.COV2.S: <https://pubmed.ncbi.nlm.nih.gov/34337124/>

Case of immunoglobulin A vasculitis after vaccination against coronavirus disease 2019: <https://pubmed.ncbi.nlm.nih.gov/34535924/>

Rapid progression of angioimmunoblastic T-cell lymphoma after BNT162b2 mRNA booster vaccination: case report: <https://www.frontiersin.org/articles/10.3389/fmed.2021.798095/>

COVID-19 mRNA vaccination-induced lymphadenopathy mimics lymphoma progression on FDG PET / CT: <https://pubmed.ncbi.nlm.nih.gov/33591026/>

Lymphadenopathy in COVID-19 vaccine recipients: diagnostic dilemma in oncology patients: <https://pubmed.ncbi.nlm.nih.gov/33625300/>

Hypermetabolic lymphadenopathy after administration of BNT162b2 mRNA vaccine Covid-19: incidence assessed by [18 F] FDG PET-CT and relevance for study interpretation: <https://pubmed.ncbi.nlm.nih.gov/33774684/>

Lymphadenopathy after COVID-19 vaccination: review of imaging findings: <https://pubmed.ncbi.nlm.nih.gov/33985872/>

Evolution of bilateral hypermetabolic axillary hypermetabolic lymphadenopathy on FDG PET/CT after 2-dose COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34735411/>

Lymphadenopathy associated with COVID-19 vaccination on FDG PET/CT: distinguishing features in adenovirus-vectored vaccine: <https://pubmed.ncbi.nlm.nih.gov/34115709/>.

COVID-19 vaccination-induced lymphadenopathy in a specialized breast imaging clinic in Israel: analysis of 163 cases: <https://pubmed.ncbi.nlm.nih.gov/34257025/>.

COVID-19 vaccine-related axillary lymphadenopathy in breast cancer patients: case series with literature review: <https://pubmed.ncbi.nlm.nih.gov/34836672/>.

Coronavirus disease vaccine 2019 mimics lymph node metastases in patients undergoing skin cancer follow-up: a single-center study: <https://pubmed.ncbi.nlm.nih.gov/34280870/>

COVID-19 post-vaccination lymphadenopathy: report of fine-needle aspiration biopsy cytologic findings: <https://pubmed.ncbi.nlm.nih.gov/34432391/>

Regional lymphadenopathy after COVID-19 vaccination: review of the literature and considerations for patient management in breast cancer care: <https://pubmed.ncbi.nlm.nih.gov/34731748/>

Subclinical axillary lymphadenopathy associated with COVID-19 vaccination on screening mammography: <https://pubmed.ncbi.nlm.nih.gov/34906409/>

Adverse events of COVID injection that may occur in children. Acute-onset supraclavicular lymphadenopathy coincident with intramuscular mRNA vaccination against COVID-19 may be related to the injection technique of the vaccine, Spain, January and February 2021: <https://pubmed.ncbi.nlm.nih.gov/33706861/>

Supraclavicular lymphadenopathy after COVID-19 vaccination in Korea: serial follow-up by ultrasonography: <https://pubmed.ncbi.nlm.nih.gov/34116295/>

Oxford-AstraZeneca COVID-19 vaccination induced lymphadenopathy on [18F] choline PET / CT, not just an FDG finding: <https://pubmed.ncbi.nlm.nih.gov/33661328/>

Biphasic anaphylaxis after exposure to the first dose of Pfizer-BioNTech COVID-19 mRNA vaccine COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34050949/>

Axillary adenopathy associated with COVID-19 vaccination: imaging findings and follow-up recommendations in 23 women: <https://pubmed.ncbi.nlm.nih.gov/33624520/>

A case of cervical lymphadenopathy following COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34141500/>

Unique imaging findings of neurologic phantosmia after Pfizer-BioNtech COVID-19 vaccination: a case report: <https://pubmed.ncbi.nlm.nih.gov/34096896/>

Thrombotic adverse events reported for Moderna, Pfizer, and Oxford-AstraZeneca COVID-19 vaccines: comparison of occurrence and clinical outcomes in the EudraVigilance database: <https://pubmed.ncbi.nlm.nih.gov/34835256/>

Unilateral lymphadenopathy after COVID-19 vaccination: a practical management plan for radiologists of all specialties: <https://pubmed.ncbi.nlm.nih.gov/33713605/>

Unilateral axillary adenopathy in the setting of COVID-19 vaccination: follow-up: <https://pubmed.ncbi.nlm.nih.gov/34298342/>

A systematic review of cases of CNS demyelination following COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34839149/>

Supraclavicular lymphadenopathy after COVID-19 vaccination: an increasing presentation in the two-week wait neck lump clinic: <https://pubmed.ncbi.nlm.nih.gov/33685772/>

COVID-19 vaccine-related axillary and cervical lymphadenopathy in patients with current or previous breast cancer and other malignancies: cross-sectional imaging findings on MRI, CT and PET-CT: <https://pubmed.ncbi.nlm.nih.gov/34719892/>

Adenopathy after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33625299/>.

Incidence of axillary adenopathy on breast imaging after vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34292295/>.

COVID-19 vaccination and lower cervical lymphadenopathy in two-week neck lump clinic: a follow-up audit: <https://pubmed.ncbi.nlm.nih.gov/33947605/>.

Cervical lymphadenopathy after coronavirus disease vaccination 2019: clinical features and implications for head and neck cancer services: <https://pubmed.ncbi.nlm.nih.gov/34526175/>

Lymphadenopathy associated with the COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33786231/>

Evolution of lymphadenopathy on PET/MRI after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33625301/>.

Autoimmune hepatitis triggered by SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34332438/>.

New-onset nephrotic syndrome after Janssen COVID-19 vaccination: case report and literature review: <https://pubmed.ncbi.nlm.nih.gov/34342187/>.

Massive cervical lymphadenopathy following vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34601889/>

ANCA glomerulonephritis following Modern COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34081948/>

Extensive longitudinal transverse myelitis following AstraZeneca COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34507942/>.

Systemic capillary extravasation syndrome after vaccination with ChAdOx1 nCoV-19 (Oxford-AstraZeneca): <https://pubmed.ncbi.nlm.nih.gov/34362727/>

Unilateral axillary lymphadenopathy related to COVID-19 vaccine: pattern on screening breast MRI allowing benign evaluation: <https://pubmed.ncbi.nlm.nih.gov/34325221/>

Axillary lymphadenopathy in patients with recent Covid-19 vaccination: a new diagnostic dilemma: <https://pubmed.ncbi.nlm.nih.gov/34825530/>.

Minimal change disease and acute kidney injury after Pfizer-BioNTech COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34000278/>

COVID-19 vaccine-induced unilateral axillary adenopathy: follow-up evaluation in the USA: <https://pubmed.ncbi.nlm.nih.gov/34655312/>.

Gastroparesis after Pfizer-BioNTech COVID-19

vaccination: <https://pubmed.ncbi.nlm.nih.gov/34187985/>.

Acute-onset supraclavicular lymphadenopathy coincident with intramuscular mRNA vaccination against COVID-19 may be related to the injection technique of the vaccine, Spain, January and February 2021: <https://pubmed.ncbi.nlm.nih.gov/33706861/>

Supraclavicular lymphadenopathy after COVID-19 vaccination in Korea: serial follow-up by ultrasonography: <https://pubmed.ncbi.nlm.nih.gov/34116295/>

Oxford-AstraZeneca COVID-19 vaccination induced lymphadenopathy on [18F] choline PET / CT, not just an FDG finding: <https://pubmed.ncbi.nlm.nih.gov/33661328/>

Biphasic anaphylaxis after exposure to the first dose of Pfizer-BioNTech COVID-19 mRNA vaccine COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34050949/>

Axillary adenopathy associated with COVID-19 vaccination: imaging findings and follow-up recommendations in 23 women: <https://pubmed.ncbi.nlm.nih.gov/33624520/>

A case of cervical lymphadenopathy following COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34141500/>

Unique imaging findings of neurologic phantosmia after Pfizer-BioNtech COVID-19 vaccination: a case report: <https://pubmed.ncbi.nlm.nih.gov/34096896/>

Thrombotic adverse events reported for Moderna, Pfizer, and Oxford-AstraZeneca COVID-19 vaccines: comparison of occurrence and clinical outcomes in the EudraVigilance database: <https://pubmed.ncbi.nlm.nih.gov/34835256/>

Unilateral lymphadenopathy after COVID-19 vaccination: a practical management plan for radiologists of all specialties: <https://pubmed.ncbi.nlm.nih.gov/33713605/>

Unilateral axillary adenopathy in the setting of COVID-19 vaccination: follow-up: <https://pubmed.ncbi.nlm.nih.gov/34298342/>

A systematic review of cases of CNS demyelination following COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34839149/>

Supraclavicular lymphadenopathy after COVID-19 vaccination: an increasing presentation in the two-week wait neck lump clinic: <https://pubmed.ncbi.nlm.nih.gov/33685772/>

COVID-19 vaccine-related axillary and cervical lymphadenopathy in patients with current or previous breast cancer and other malignancies: cross-sectional imaging findings on MRI, CT and PET-CT: <https://pubmed.ncbi.nlm.nih.gov/34719892/>

Adenopathy after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33625299/>.

Incidence of axillary adenopathy on breast imaging after vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34292295/>.

COVID-19 vaccination and lower cervical lymphadenopathy in two-week neck lump clinic: a follow-up audit: <https://pubmed.ncbi.nlm.nih.gov/33947605/>.

Cervical lymphadenopathy after coronavirus disease vaccination 2019: clinical features and implications for head and neck cancer services: <https://pubmed.ncbi.nlm.nih.gov/34526175/>

Lymphadenopathy associated with the COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/33786231/>

Evolution of lymphadenopathy on PET/MRI after COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/33625301/>.

Autoimmune hepatitis triggered by SARS-CoV-2 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34332438/>.

New-onset nephrotic syndrome after Janssen COVID-19 vaccination: case report and literature review: <https://pubmed.ncbi.nlm.nih.gov/34342187/>.

Massive cervical lymphadenopathy following vaccination with COVID-19: <https://pubmed.ncbi.nlm.nih.gov/34601889/>

ANCA glomerulonephritis following Modern COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34081948/>

Extensive longitudinal transverse myelitis following AstraZeneca COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34507942/>.

Systemic capillary extravasation syndrome after vaccination with ChAdOx1 nCoV-19 (Oxford-AstraZeneca): <https://pubmed.ncbi.nlm.nih.gov/34362727/>

Unilateral axillary lymphadenopathy related to COVID-19 vaccine: pattern on screening breast MRI allowing benign evaluation: <https://pubmed.ncbi.nlm.nih.gov/34325221/>

Axillary lymphadenopathy in patients with recent Covid-19 vaccination: a new diagnostic dilemma: <https://pubmed.ncbi.nlm.nih.gov/34825530/>.

Minimal change disease and acute kidney injury after Pfizer-BioNTech COVID-19 vaccine: <https://pubmed.ncbi.nlm.nih.gov/34000278/>

COVID-19 vaccine-induced unilateral axillary adenopathy: follow-up evaluation in the USA: <https://pubmed.ncbi.nlm.nih.gov/34655312/>.

Gastroparesis after Pfizer-BioNTech COVID-19 vaccination: <https://pubmed.ncbi.nlm.nih.gov/34187985/>.

Abbate, A., Gavin, J., Madanchi, N., Kim, C., Shah, P. R., Klein, K., . . . Danielides, S. (2021). Fulminant myocarditis and systemic hyperinflammation temporally associated with BNT162b2 mRNA COVID-19 vaccination in two patients. *Int J Cardiol*, 340, 119-121. doi:10.1016/j.ijcard.2021.08.018. <https://www.ncbi.nlm.nih.gov/pubmed/34416319>

Abu Mouch, S., Roguin, A., Hellou, E., Ishai, A., Shoshan, U., Mahamid, L., . . . Berar Yanay, N. (2021). Myocarditis following COVID-19 mRNA vaccination. *Vaccine*, 39(29), 3790-3793. doi:10.1016/j.vaccine.2021.05.087. <https://www.ncbi.nlm.nih.gov/pubmed/34092429>

Albert, E., Aurigemma, G., Saucedo, J., & Gerson, D. S. (2021). Myocarditis following COVID-19 vaccination. *Radiol Case Rep*, 16(8), 2142-2145. doi:10.1016/j.radcr.2021.05.033. <https://www.ncbi.nlm.nih.gov/pubmed/34025885>

Aye, Y. N., Mai, A. S., Zhang, A., Lim, O. Z. H., Lin, N., Ng, C. H., . . . Chew, N. W. S. (2021). Acute Myocardial Infarction and Myocarditis following COVID-19 Vaccination. *QJM*. doi:10.1093/qjmed/hcab252. <https://www.ncbi.nlm.nih.gov/pubmed/34586408>

Azir, M., Inman, B., Webb, J., & Tannenbaum, L. (2021). STEMI Mimic: Focal Myocarditis in an Adolescent Patient After mRNA COVID-19 Vaccine. *J Emerg Med*, 61(6), e129-e132. doi:10.1016/j.jemermed.2021.09.017. <https://www.ncbi.nlm.nih.gov/pubmed/34756746>

Barda, N., Dagan, N., Ben-Shlomo, Y., Kepten, E., Waxman, J., Ohana, R., . . . Balicer, R. D. (2021). Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting. *N Engl J Med*, 385(12), 1078-1090. doi:10.1056/NEJMoa2110475. <https://www.ncbi.nlm.nih.gov/pubmed/34432976>

Bhandari, M., Pradhan, A., Vishwakarma, P., & Sethi, R. (2021). Coronavirus and cardiovascular manifestations- getting to the heart of the matter. *World J Cardiol*, 13(10), 556-565. doi:10.4330/wjc.v13.i10.556. <https://www.ncbi.nlm.nih.gov/pubmed/34754400>

Bozkurt, B., Kamat, I., & Hotez, P. J. (2021). Myocarditis With COVID-19 mRNA Vaccines. *Circulation*, 144(6), 471-484. doi:10.1161/CIRCULATIONAHA.121.056135. <https://www.ncbi.nlm.nih.gov/pubmed/34281357>

Buchhorn, R., Meyer, C., Schulze-Forster, K., Junker, J., & Heidecke, H. (2021). Autoantibody Release in Children after Corona Virus mRNA Vaccination: A Risk Factor of Multisystem Inflammatory Syndrome? *Vaccines (Basel)*, 9(11). doi:10.3390/vaccines9111353. <https://www.ncbi.nlm.nih.gov/pubmed/34835284>

Calcaterra, G., Bassareo, P. P., Barilla, F., Romeo, F., & Mehta, J. L. (2022). Concerning the unexpected prothrombotic state following some coronavirus disease 2019 vaccines. *J Cardiovasc Med (Hagerstown)*, 23(2), 71-74. doi:10.2459/JCM.0000000000001232. <https://www.ncbi.nlm.nih.gov/pubmed/34366403>

Calcaterra, G., Mehta, J. L., de Gregorio, C., Butera, G., Neroni, P., Fanos, V., & Bassareo, P. P. (2021). COVID 19 Vaccine for Adolescents. Concern about Myocarditis and Pericarditis. *Pediatr Rep*, 13(3), 530-533. doi:10.3390/pediatric13030061. <https://www.ncbi.nlm.nih.gov/pubmed/34564344>

Chai, Q., Nygaard, U., Schmidt, R. C., Zaremba, T., Moller, A. M., & Thorvig, C. M. (2022). Multisystem inflammatory syndrome in a male adolescent after his second Pfizer-BioNTech COVID-19 vaccine. *Acta Paediatr*, 111(1), 125-127. doi:10.1111/apa.16141. <https://www.ncbi.nlm.nih.gov/pubmed/34617315>

Chamling, B., Vehof, V., Drakos, S., Weil, M., Stalling, P., Vahlhaus, C., . . . Yilmaz, A. (2021). Occurrence of acute infarct-like myocarditis following COVID-19 vaccination: just an accidental co-incidence or rather vaccination-associated autoimmune myocarditis? *Clin Res Cardiol*, 110(11), 1850-1854. doi:10.1007/s00392-021-01916-w. <https://www.ncbi.nlm.nih.gov/pubmed/34333695>

Chang, J. C., & Hawley, H. B. (2021). Vaccine-Associated Thrombocytopenia and Thrombosis: Venous Endotheliopathy Leading to Venous Combined Micro-Macrothrombosis. *Medicina (Kaunas)*, 57(11). doi:10.3390/medicina57111163. <https://www.ncbi.nlm.nih.gov/pubmed/34833382>

Chelala, L., Jeudy, J., Hossain, R., Rosenthal, G., Pietris, N., & White, C. (2021). Cardiac MRI Findings of Myocarditis After COVID-19 mRNA Vaccination in Adolescents. *AJR Am J Roentgenol*.

doi:10.2214/AJR.21.26853. <https://www.ncbi.nlm.nih.gov/pubmed/34704459>

Choi, S., Lee, S., Seo, J. W., Kim, M. J., Jeon, Y. H., Park, J. H., . . . Yeo, N. S. (2021). Myocarditis-induced Sudden Death after BNT162b2 mRNA COVID-19 Vaccination in Korea: Case Report Focusing on Histopathological Findings. *J Korean Med Sci*, 36(40), e286. doi:10.3346/jkms.2021.36.e286. <https://www.ncbi.nlm.nih.gov/pubmed/34664804>

Chouchana, L., Blet, A., Al-Khalaf, M., Kafil, T. S., Nair, G., Robblee, J., . . . Liu, P. P. (2021). Features of Inflammatory Heart Reactions Following mRNA COVID-19 Vaccination at a Global Level. *Clin Pharmacol Ther*.

doi:10.1002/cpt.2499. <https://www.ncbi.nlm.nih.gov/pubmed/34860360>

Chua, G. T., Kwan, M. Y. W., Chui, C. S. L., Smith, R. D., Cheung, E. C., Tian, T., . . . Ip, P. (2021). Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination. *Clin Infect Dis*.

doi:10.1093/cid/ciab989. <https://www.ncbi.nlm.nih.gov/pubmed/34849657>

Clarke, R., & Ioannou, A. (2021). Should T2 mapping be used in cases of recurrent myocarditis to differentiate between the acute inflammation and chronic scar? *J Pediatr*.

doi:10.1016/j.jpeds.2021.12.026. <https://www.ncbi.nlm.nih.gov/pubmed/34933012>

Colaneri, M., De Filippo, M., Licari, A., Marseglia, A., Maiocchi, L., Ricciardi, A., . . . Bruno, R. (2021). COVID vaccination and asthma exacerbation: might there be a link? *Int J Infect Dis*, 112, 243-246.

doi:10.1016/j.ijid.2021.09.026. <https://www.ncbi.nlm.nih.gov/pubmed/34547487>

Das, B. B., Kohli, U., Ramachandran, P., Nguyen, H. H., Greil, G., Hussain, T., . . . Khan, D. (2021). Myopericarditis after messenger RNA Coronavirus Disease 2019 Vaccination in Adolescents 12 to 18 Years of Age. *J Pediatr*, 238, 26-32 e21.

doi:10.1016/j.jpeds.2021.07.044. <https://www.ncbi.nlm.nih.gov/pubmed/34339728>

Das, B. B., Moskowitz, W. B., Taylor, M. B., & Palmer, A. (2021). Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination: What Do We Know So Far? *Children (Basel)*, 8(7).

doi:10.3390/children8070607. <https://www.ncbi.nlm.nih.gov/pubmed/34356586>

Deb, A., Abdelmalek, J., Iwuji, K., & Nugent, K. (2021). Acute Myocardial Injury Following COVID-19 Vaccination: A Case Report and Review of Current Evidence from Vaccine Adverse Events Reporting System Database. *J Prim Care Community Health*, 12, 21501327211029230.

doi:10.1177/21501327211029230. <https://www.ncbi.nlm.nih.gov/pubmed/34219532>

Dickey, J. B., Albert, E., Badr, M., Laraja, K. M., Sena, L. M., Gerson, D. S., . . . Aurigemma, G. P. (2021). A Series of Patients With Myocarditis Following SARS-CoV-2 Vaccination With mRNA-1279 and BNT162b2. *JACC Cardiovasc Imaging*, 14(9), 1862-1863. doi:10.1016/j.jcmg.2021.06.003. <https://www.ncbi.nlm.nih.gov/pubmed/34246585>

Dimopoulou, D., Spyridis, N., Vartzelis, G., Tsolia, M. N., & Maritsi, D. N. (2021). Safety and tolerability of the COVID-19 mRNA-vaccine in adolescents with juvenile idiopathic arthritis on treatment with TNF-inhibitors. *Arthritis Rheumatol*.

doi:10.1002/art.41977. <https://www.ncbi.nlm.nih.gov/pubmed/34492161>

Dimopoulou, D., Vartzelis, G., Dasoula, F., Tsolia, M., & Maritsi, D. (2021). Immunogenicity of the COVID-19 mRNA vaccine in adolescents with juvenile idiopathic arthritis on treatment with TNF inhibitors. *Ann Rheum Dis*. doi:10.1136/annrheumdis-2021-221607. <https://www.ncbi.nlm.nih.gov/pubmed/34844930>

Ehrlich, P., Klingel, K., Ohlmann-Knafo, S., Huttinger, S., Sood, N., Pickuth, D., & Kindermann, M. (2021). Biopsy-proven lymphocytic myocarditis following first mRNA COVID-19 vaccination in a 40-year-old male: case report. *Clin Res Cardiol*, 110(11), 1855-1859. doi:10.1007/s00392-021-01936-6. <https://www.ncbi.nlm.nih.gov/pubmed/34487236>

El Sahly, H. M., Baden, L. R., Essink, B., Doblecki-Lewis, S., Martin, J. M., Anderson, E. J., . . . Group, C. S. (2021). Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase. *N Engl J Med*, 385(19), 1774-1785.

doi:10.1056/NEJMoa2113017. <https://www.ncbi.nlm.nih.gov/pubmed/34551225>

Facetti, S., Giraldi, M., Vecchi, A. L., Rogiani, S., & Nassiacos, D. (2021). [Acute myocarditis in a young adult two days after Pfizer vaccination]. *G Ital Cardiol (Rome)*, 22(11), 891-893. doi:10.1714/3689.36746. <https://www.ncbi.nlm.nih.gov/pubmed/34709227>

Fazlollahi, A., Zahmatyar, M., Noori, M., Nejadghaderi, S. A., Sullman, M. J. M., Shekariz-Foumani, R., . . . Safiri, S. (2021). Cardiac complications following mRNA COVID-19 vaccines: A systematic review of case reports and case series. *Rev Med Virol*, e2318. doi:10.1002/rmv.2318. <https://www.ncbi.nlm.nih.gov/pubmed/34921468>

Fazolo, T., Lima, K., Fontoura, J. C., de Souza, P. O., Hilario, G., Zorzetto, R., . . .

Bonorino, C. (2021). Pediatric COVID-19 patients in South Brazil show abundant viral mRNA and strong specific anti-viral responses. *Nat Commun*, 12(1), 6844.

doi:10.1038/s41467-021-27120-y. <https://www.ncbi.nlm.nih.gov/pubmed/34824230>

Fikenzer, S., & Laufs, U. (2021). Correction to: Response to Letter to the editors referring to

Fikenzer, S., Uhe, T., Lavall, D., Rudolph, U., Falz, R., Busse, M., Hepp, P., & Laufs, U.

(2020). Effects of surgical and FFP2/N95 face masks on cardiopulmonary exercise capacity. *Clinical research in cardiology: official journal of the German Cardiac Society*, 1-9.

Advance online publication. <https://doi.org/10.1007/s00392-020-01704-y>. *Clin Res Cardiol*, 110(8), 1352. doi:10.1007/s00392-021-01896-

x. <https://www.ncbi.nlm.nih.gov/pubmed/34170372>

Foltran, D., Delmas, C., Flumian, C., De Paoli, P., Salvo, F., Gautier, S., . . . Montastruc, F.

(2021). Myocarditis and Pericarditis in Adolescents after First and Second doses of mRNA COVID-19 Vaccines. *Eur Heart J Qual Care Clin Outcomes*.

doi:10.1093/ehjqcco/qcab090. <https://www.ncbi.nlm.nih.gov/pubmed/34849667>

Forgacs, D., Jang, H., Abreu, R. B., Hanley, H. B., Gattiker, J. L., Jefferson, A. M., & Ross, T. M. (2021). SARS-CoV-2 mRNA Vaccines Elicit Different Responses in

Immunologically Naive and Pre-Immune Humans. *Front Immunol*, 12, 728021.

doi:10.3389/fimmu.2021.728021. <https://www.ncbi.nlm.nih.gov/pubmed/34646267>

Furer, V., Eviatar, T., Zisman, D., Peleg, H., Paran, D., Levartovsky, D., . . . Elkayam, O.

(2021). Immunogenicity and safety of the BNT162b2 mRNA COVID-19 vaccine in adult patients with autoimmune inflammatory rheumatic diseases and in the general population: a multicentre study. *Ann Rheum Dis*, 80(10), 1330-1338. doi:10.1136/annrheumdis-2021-

220647. <https://www.ncbi.nlm.nih.gov/pubmed/34127481>

Galindo, R., Chow, H., & Rongkavilit, C. (2021). COVID-19 in Children: Clinical

Manifestations and Pharmacologic Interventions Including Vaccine Trials. *Pediatr Clin North Am*, 68(5), 961-976.

doi:10.1016/j.pcl.2021.05.004. <https://www.ncbi.nlm.nih.gov/pubmed/34538306>

Gargano, J. W., Wallace, M., Hadler, S. C., Langley, G., Su, J. R., Oster, M. E., . . . Oliver,

S. E. (2021). Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices – United States, June 2021. *MMWR Morb Mortal Wkly Rep*, 70(27), 977-982.

doi:10.15585/mmwr.mm7027e2. <https://www.ncbi.nlm.nih.gov/pubmed/34237049>

- Gatti, M., Raschi, E., Moretti, U., Ardizzoni, A., Poluzzi, E., & Diemberger, I. (2021). Influenza Vaccination and Myo-Pericarditis in Patients Receiving Immune Checkpoint Inhibitors: Investigating the Likelihood of Interaction through the Vaccine Adverse Event Reporting System and Vigibase. *Vaccines (Basel)*, 9(1).
doi:10.3390/vaccines9010019. <https://www.ncbi.nlm.nih.gov/pubmed/33406694>
- Gautam, N., Saluja, P., Fudim, M., Jambhekar, K., Pandey, T., & Al'Aref, S. (2021). A Late Presentation of COVID-19 Vaccine-Induced Myocarditis. *Cureus*, 13(9), e17890.
doi:10.7759/cureus.17890. <https://www.ncbi.nlm.nih.gov/pubmed/34660088>
- Gellad, W. F. (2021). Myocarditis after vaccination against covid-19. *BMJ*, 375, n3090.
doi:10.1136/bmj.n3090. <https://www.ncbi.nlm.nih.gov/pubmed/34916217>
- Greenhawt, M., Abrams, E. M., Shaker, M., Chu, D. K., Khan, D., Akin, C., . . . Golden, D. B. K. (2021). The Risk of Allergic Reaction to SARS-CoV-2 Vaccines and Recommended Evaluation and Management: A Systematic Review, Meta-Analysis, GRADE Assessment, and International Consensus Approach. *J Allergy Clin Immunol Pract*, 9(10), 3546-3567.
doi:10.1016/j.jaip.2021.06.006. <https://www.ncbi.nlm.nih.gov/pubmed/34153517>
- Haaf, P., Kuster, G. M., Mueller, C., Berger, C. T., Monney, P., Burger, P., . . . Tanner, F. C. (2021). The very low risk of myocarditis and pericarditis after mRNA COVID-19 vaccination should not discourage vaccination. *Swiss Med Wkly*, 151, w30087.
doi:10.4414/smw.2021.w30087. <https://www.ncbi.nlm.nih.gov/pubmed/34668687>
- Hasnie, A. A., Hasnie, U. A., Patel, N., Aziz, M. U., Xie, M., Lloyd, S. G., & Prabhu, S. D. (2021). Perimyocarditis following first dose of the mRNA-1273 SARS-CoV-2 (Moderna) vaccine in a healthy young male: a case report. *BMC Cardiovasc Disord*, 21(1), 375.
doi:10.1186/s12872-021-02183-3. <https://www.ncbi.nlm.nih.gov/pubmed/34348657>
- Hause, A. M., Gee, J., Baggs, J., Abara, W. E., Marquez, P., Thompson, D., . . . Shay, D. K. (2021). COVID-19 Vaccine Safety in Adolescents Aged 12-17 Years – United States, December 14, 2020-July 16, 2021. *MMWR Morb Mortal Wkly Rep*, 70(31), 1053-1058.
doi:10.15585/mmwr.mm7031e1. <https://www.ncbi.nlm.nih.gov/pubmed/34351881>
- Helms, J. M., Ansteatt, K. T., Roberts, J. C., Kamatam, S., Foong, K. S., Labayog, J. S., & Tarantino, M. D. (2021). Severe, Refractory Immune Thrombocytopenia Occurring After SARS-CoV-2 Vaccine. *J Blood Med*, 12, 221-224.
doi:10.2147/JBM.S307047. <https://www.ncbi.nlm.nih.gov/pubmed/33854395>

Hippisley-Cox, J., Patone, M., Mei, X. W., Saatci, D., Dixon, S., Khunti, K., . . . Coupland, C. A. C. (2021). Risk of thrombocytopenia and thromboembolism after covid-19 vaccination and SARS-CoV-2 positive testing: self-controlled case series study. *BMJ*, 374, n1931. doi:10.1136/bmj.n1931. <https://www.ncbi.nlm.nih.gov/pubmed/34446426>

Ho, J. S., Sia, C. H., Ngiam, J. N., Loh, P. H., Chew, N. W., Kong, W. K., & Poh, K. K. (2021). A review of COVID-19 vaccination and the reported cardiac manifestations. *Singapore Med J*. doi:10.11622/smedj.2021210. <https://www.ncbi.nlm.nih.gov/pubmed/34808708>

Iguchi, T., Umeda, H., Kojima, M., Kanno, Y., Tanaka, Y., Kinoshita, N., & Sato, D. (2021). Cumulative Adverse Event Reporting of Anaphylaxis After mRNA COVID-19 Vaccine (Pfizer-BioNTech) Injections in Japan: The First-Month Report. *Drug Saf*, 44(11), 1209-1214. doi:10.1007/s40264-021-01104-9. <https://www.ncbi.nlm.nih.gov/pubmed/34347278>

In brief: Myocarditis with the Pfizer/BioNTech and Moderna COVID-19 vaccines. (2021). *Med Lett Drugs Ther*, 63(1629), e9. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/34544112><https://www.ncbi.nlm.nih.gov/pubmed/3454412>

Ioannou, A. (2021a). Myocarditis should be considered in those with a troponin rise and unobstructed coronary arteries following Pfizer-BioNTech COVID-19 vaccination. *QJM*. doi:10.1093/qjmed/hcab231. <https://www.ncbi.nlm.nih.gov/pubmed/34463755>

Ioannou, A. (2021b). T2 mapping should be utilised in cases of suspected myocarditis to confirm an acute inflammatory process. *QJM*. doi:10.1093/qjmed/hcab326. <https://www.ncbi.nlm.nih.gov/pubmed/34931681>

Isaak, A., Feisst, A., & Luetkens, J. A. (2021). Myocarditis Following COVID-19 Vaccination. *Radiology*, 301(1), E378-E379. doi:10.1148/radiol.2021211766. <https://www.ncbi.nlm.nih.gov/pubmed/34342500>

Istampoulouoglou, I., Dimitriou, G., Spani, S., Christ, A., Zimmermanns, B., Koechlin, S., . . . Leuppi-Taegtmeier, A. B. (2021). Myocarditis and pericarditis in association with COVID-19 mRNA-vaccination: cases from a regional pharmacovigilance centre. *Glob Cardiol Sci Pract*, 2021(3), e202118. doi:10.21542/gcsp.2021.18. <https://www.ncbi.nlm.nih.gov/pubmed/34805376>

- Jaafar, R., Boschi, C., Aherfi, S., Bancod, A., Le Bideau, M., Edouard, S., . . . La Scola, B. (2021). High Individual Heterogeneity of Neutralizing Activities against the Original Strain and Nine Different Variants of SARS-CoV-2. *Viruses*, 13(11). doi:10.3390/v13112177. <https://www.ncbi.nlm.nih.gov/pubmed/34834983>
- Jain, S. S., Steele, J. M., Fonseca, B., Huang, S., Shah, S., Maskatia, S. A., . . . Grosse-Wortmann, L. (2021). COVID-19 Vaccination-Associated Myocarditis in Adolescents. *Pediatrics*, 148(5). doi:10.1542/peds.2021-053427. <https://www.ncbi.nlm.nih.gov/pubmed/34389692>
- Jhaveri, R., Adler-Shohet, F. C., Blyth, C. C., Chiotos, K., Gerber, J. S., Green, M., . . . Zaoutis, T. (2021). Weighing the Risks of Perimyocarditis With the Benefits of SARS-CoV-2 mRNA Vaccination in Adolescents. *J Pediatric Infect Dis Soc*, 10(10), 937-939. doi:10.1093/jpids/piab061. <https://www.ncbi.nlm.nih.gov/pubmed/34270752>
- Kaneta, K., Yokoi, K., Jojima, K., Kotooka, N., & Node, K. (2021). Young Male With Myocarditis Following mRNA-1273 Vaccination Against Coronavirus Disease-2019 (COVID-19). *Circ J*. doi:10.1253/circj.CJ-21-0818. <https://www.ncbi.nlm.nih.gov/pubmed/34744118>
- Kaul, R., Sreenivasan, J., Goel, A., Malik, A., Bandyopadhyay, D., Jin, C., . . . Panza, J. A. (2021). Myocarditis following COVID-19 vaccination. *Int J Cardiol Heart Vasc*, 36, 100872. doi:10.1016/j.ijcha.2021.100872. <https://www.ncbi.nlm.nih.gov/pubmed/34568540>
- Khogali, F., & Abdelrahman, R. (2021). Unusual Presentation of Acute Perimyocarditis Following SARS-COV-2 mRNA-1237 Moderna Vaccination. *Cureus*, 13(7), e16590. doi:10.7759/cureus.16590. <https://www.ncbi.nlm.nih.gov/pubmed/34447639>
- Kim, H. W., Jenista, E. R., Wendell, D. C., Azevedo, C. F., Campbell, M. J., Darty, S. N., . . . Kim, R. J. (2021). Patients With Acute Myocarditis Following mRNA COVID-19 Vaccination. *JAMA Cardiol*, 6(10), 1196-1201. doi:10.1001/jamacardio.2021.2828. <https://www.ncbi.nlm.nih.gov/pubmed/34185046>
- Kim, I. C., Kim, H., Lee, H. J., Kim, J. Y., & Kim, J. Y. (2021). Cardiac Imaging of Acute Myocarditis Following COVID-19 mRNA Vaccination. *J Korean Med Sci*, 36(32), e229. doi:10.3346/jkms.2021.36.e229. <https://www.ncbi.nlm.nih.gov/pubmed/34402228>
- King, W. W., Petersen, M. R., Matar, R. M., Budweg, J. B., Cuervo Pardo, L., & Petersen, J. W. (2021). Myocarditis following mRNA vaccination against SARS-CoV-2, a case series.

Am Heart J Plus, 8, 100042.

doi:10.1016/j.ahjo.2021.100042. <https://www.ncbi.nlm.nih.gov/pubmed/34396358>

Klein, N. P., Lewis, N., Goddard, K., Fireman, B., Zerbo, O., Hanson, K. E., . . . Weintraub, E. S. (2021). Surveillance for Adverse Events After COVID-19 mRNA Vaccination. *JAMA*, 326(14), 1390-1399.

doi:10.1001/jama.2021.15072. <https://www.ncbi.nlm.nih.gov/pubmed/34477808>

Klimek, L., Bergmann, K. C., Brehler, R., Pfutzner, W., Zuberbier, T., Hartmann, K., . . . Worm, M. (2021). Practical handling of allergic reactions to COVID-19 vaccines: A position paper from German and Austrian Allergy Societies AeDA, DGAKI, GPA and OGAI.

Allergo J Int, 1-17. doi:10.1007/s40629-021-00165-

7. <https://www.ncbi.nlm.nih.gov/pubmed/33898162>

Klimek, L., Novak, N., Hamelmann, E., Werfel, T., Wagenmann, M., Taube, C., . . . Worm, M. (2021). Severe allergic reactions after COVID-19 vaccination with the Pfizer/BioNTech vaccine in Great Britain and USA: Position statement of the German Allergy Societies:

Medical Association of German Allergologists (AeDA), German Society for Allergology and Clinical Immunology (DGAKI) and Society for Pediatric Allergology and

Environmental Medicine (GPA). *Allergo J Int*, 30(2), 51-55. doi:10.1007/s40629-020-

00160-4. <https://www.ncbi.nlm.nih.gov/pubmed/33643776>

Kohli, U., Desai, L., Chowdhury, D., Harahsheh, A. S., Yonts, A. B., Ansong, A., . . . Ang, J. Y. (2021). mRNA Coronavirus-19 Vaccine-Associated Myopericarditis in Adolescents: A Survey Study. *J Pediatr*.

doi:10.1016/j.jpeds.2021.12.025. <https://www.ncbi.nlm.nih.gov/pubmed/34952008>

Kostoff, R. N., Calina, D., Kanduc, D., Briggs, M. B., Vlachoyiannopoulos, P., Svistunov, A. A., & Tsatsakis, A. (2021a). Erratum to “Why are we vaccinating children against COVID-19?” [*Toxicol. Rep.* 8C (2021) 1665-1684 / 1193]. *Toxicol Rep*, 8, 1981.

doi:10.1016/j.toxrep.2021.10.003. <https://www.ncbi.nlm.nih.gov/pubmed/34642628>

Kostoff, R. N., Calina, D., Kanduc, D., Briggs, M. B., Vlachoyiannopoulos, P., Svistunov, A. A., & Tsatsakis, A. (2021b). Why are we vaccinating children against COVID-19? *Toxicol Rep*, 8, 1665-1684.

doi:10.1016/j.toxrep.2021.08.010. <https://www.ncbi.nlm.nih.gov/pubmed/34540594>

Kremsner, P. G., Mann, P., Kroidl, A., Leroux-Roels, I., Schindler, C., Gabor, J. J., . . .

Group, C.-N.-S. (2021). Safety and immunogenicity of an mRNA-lipid nanoparticle vaccine

candidate against SARS-CoV-2 : A phase 1 randomized clinical trial. *Wien Klin Wochenschr*, 133(17-18), 931-941. doi:10.1007/s00508-021-01922-y. <https://www.ncbi.nlm.nih.gov/pubmed/34378087>

Kustin, T., Harel, N., Finkel, U., Perchik, S., Harari, S., Tahor, M., . . . Stern, A. (2021). Evidence for increased breakthrough rates of SARS-CoV-2 variants of concern in BNT162b2-mRNA-vaccinated individuals. *Nat Med*, 27(8), 1379-1384. doi:10.1038/s41591-021-01413-7. <https://www.ncbi.nlm.nih.gov/pubmed/34127854>

Kwan, M. Y. W., Chua, G. T., Chow, C. B., Tsao, S. S. L., To, K. K. W., Yuen, K. Y., . . . Ip, P. (2021). mRNA COVID vaccine and myocarditis in adolescents. *Hong Kong Med J*, 27(5), 326-327. doi:10.12809/hkmj215120. <https://www.ncbi.nlm.nih.gov/pubmed/34393110>

Lee, E., Chew, N. W. S., Ng, P., & Yeo, T. J. (2021). Reply to “Letter to the editor: Myocarditis should be considered in those with a troponin rise and unobstructed coronary arteries following PfizerBioNTech COVID-19 vaccination”. *QJM*. doi:10.1093/qjmed/hcab232. <https://www.ncbi.nlm.nih.gov/pubmed/34463770>

Lee, E. J., Cines, D. B., Gernsheimer, T., Kessler, C., Michel, M., Tarantino, M. D., . . . Bussel, J. B. (2021). Thrombocytopenia following Pfizer and Moderna SARS-CoV-2 vaccination. *Am J Hematol*, 96(5), 534-537. doi:10.1002/ajh.26132. <https://www.ncbi.nlm.nih.gov/pubmed/33606296>

Levin, D., Shimon, G., Fadlon-Derai, M., Gershovitz, L., Shovali, A., Sebbag, A., . . . Gordon, B. (2021). Myocarditis following COVID-19 vaccination – A case series. *Vaccine*, 39(42), 6195-6200. doi:10.1016/j.vaccine.2021.09.004. <https://www.ncbi.nlm.nih.gov/pubmed/34535317>

Li, J., Hui, A., Zhang, X., Yang, Y., Tang, R., Ye, H., . . . Zhu, F. (2021). Safety and immunogenicity of the SARS-CoV-2 BNT162b1 mRNA vaccine in younger and older Chinese adults: a randomized, placebo-controlled, double-blind phase 1 study. *Nat Med*, 27(6), 1062-1070. doi:10.1038/s41591-021-01330-9. <https://www.ncbi.nlm.nih.gov/pubmed/33888900>

Li, M., Yuan, J., Lv, G., Brown, J., Jiang, X., & Lu, Z. K. (2021). Myocarditis and Pericarditis following COVID-19 Vaccination: Inequalities in Age and Vaccine Types. *J Pers Med*, 11(11). doi:10.3390/jpm11111106. <https://www.ncbi.nlm.nih.gov/pubmed/34834458>

Lim, Y., Kim, M. C., Kim, K. H., Jeong, I. S., Cho, Y. S., Choi, Y. D., & Lee, J. E. (2021). Case Report: Acute Fulminant Myocarditis and Cardiogenic Shock After Messenger RNA Coronavirus Disease 2019 Vaccination Requiring Extracorporeal Cardiopulmonary Resuscitation. *Front Cardiovasc Med*, 8, 758996.

doi:10.3389/fcvm.2021.758996. <https://www.ncbi.nlm.nih.gov/pubmed/34778411>

Long, S. S. (2021). Important Insights into Myopericarditis after the Pfizer mRNA COVID-19 Vaccination in Adolescents. *J Pediatr*, 238, 5.

doi:10.1016/j.jpeds.2021.07.057. <https://www.ncbi.nlm.nih.gov/pubmed/34332972>

Luk, A., Clarke, B., Dahdah, N., Ducharme, A., Krahn, A., McCrindle, B., . . . McDonald, M. (2021). Myocarditis and Pericarditis After COVID-19 mRNA Vaccination: Practical Considerations for Care Providers. *Can J Cardiol*, 37(10), 1629-1634.

doi:10.1016/j.cjca.2021.08.001. <https://www.ncbi.nlm.nih.gov/pubmed/34375696>

Madelon, N., Lauper, K., Breville, G., Sabater Royo, I., Goldstein, R., Andrey, D. O., . . . Eberhardt, C. S. (2021). Robust T cell responses in anti-CD20 treated patients following COVID-19 vaccination: a prospective cohort study. *Clin Infect Dis*.

doi:10.1093/cid/ciab954. <https://www.ncbi.nlm.nih.gov/pubmed/34791081>

Mangat, C., & Milosavljevic, N. (2021). BNT162b2 Vaccination during Pregnancy Protects Both the Mother and Infant: Anti-SARS-CoV-2 S Antibodies Persistently Positive in an Infant at 6 Months of Age. *Case Rep Pediatr*, 2021, 6901131.

doi:10.1155/2021/6901131. <https://www.ncbi.nlm.nih.gov/pubmed/34676123>

Mark, C., Gupta, S., Punnett, A., Upton, J., Orkin, J., Atkinson, A., . . . Alexander, S. (2021). Safety of administration of BNT162b2 mRNA (Pfizer-BioNTech) COVID-19 vaccine in youths and young adults with a history of acute lymphoblastic leukemia and allergy to PEG-asparaginase. *Pediatr Blood Cancer*, 68(11), e29295.

doi:10.1002/pbc.29295. <https://www.ncbi.nlm.nih.gov/pubmed/34398511>

Martins-Filho, P. R., Quintans-Junior, L. J., de Souza Araujo, A. A., Sposato, K. B., Souza Tavares, C. S., Gurgel, R. Q., . . . Santos, V. S. (2021). Socio-economic inequalities and COVID-19 incidence and mortality in Brazilian children: a nationwide register-based study. *Public Health*, 190, 4-6.

doi:10.1016/j.puhe.2020.11.005. <https://www.ncbi.nlm.nih.gov/pubmed/33316478>

- McLean, K., & Johnson, T. J. (2021). Myopericarditis in a previously healthy adolescent male following COVID-19 vaccination: A case report. *Acad Emerg Med*, 28(8), 918-921. doi:10.1111/acem.14322. <https://www.ncbi.nlm.nih.gov/pubmed/34133825>
- Mevorach, D., Anis, E., Cedar, N., Bromberg, M., Haas, E. J., Nadir, E., . . . Alroy-Preis, S. (2021). Myocarditis after BNT162b2 mRNA Vaccine against Covid-19 in Israel. *N Engl J Med*, 385(23), 2140-2149. doi:10.1056/NEJMoa2109730. <https://www.ncbi.nlm.nih.gov/pubmed/34614328>
- Minocha, P. K., Better, D., Singh, R. K., & Hoque, T. (2021). Recurrence of Acute Myocarditis Temporally Associated with Receipt of the mRNA Coronavirus Disease 2019 (COVID-19) Vaccine in a Male Adolescent. *J Pediatr*, 238, 321-323. doi:10.1016/j.jpeds.2021.06.035. <https://www.ncbi.nlm.nih.gov/pubmed/34166671>
- Mizrahi, B., Lotan, R., Kalkstein, N., Peretz, A., Perez, G., Ben-Tov, A., . . . Patalon, T. (2021). Correlation of SARS-CoV-2-breakthrough infections to time-from-vaccine. *Nat Commun*, 12(1), 6379. doi:10.1038/s41467-021-26672-3. <https://www.ncbi.nlm.nih.gov/pubmed/34737312>
- Moffitt, K., Cheung, E., Yeung, T., Stamoulis, C., & Malley, R. (2021). Analysis of *Staphylococcus aureus* Transcriptome in Pediatric Soft Tissue Abscesses and Comparison to Murine Infections. *Infect Immun*, 89(4). doi:10.1128/IAI.00715-20. <https://www.ncbi.nlm.nih.gov/pubmed/33526560>
- Mohamed, L., Madsen, A. M. R., Schaltz-Buchholzer, F., Ostenfeld, A., Netea, M. G., Benn, C. S., & Kofoed, P. E. (2021). Reactivation of BCG vaccination scars after vaccination with mRNA-Covid-vaccines: two case reports. *BMC Infect Dis*, 21(1), 1264. doi:10.1186/s12879-021-06949-0. <https://www.ncbi.nlm.nih.gov/pubmed/34930152>
- Montgomery, J., Ryan, M., Engler, R., Hoffman, D., McClenathan, B., Collins, L., . . . Cooper, L. T., Jr. (2021). Myocarditis Following Immunization With mRNA COVID-19 Vaccines in Members of the US Military. *JAMA Cardiol*, 6(10), 1202-1206. doi:10.1001/jamacardio.2021.2833. <https://www.ncbi.nlm.nih.gov/pubmed/34185045>
- Murakami, Y., Shinohara, M., Oka, Y., Wada, R., Noike, R., Ohara, H., . . . Ikeda, T. (2021). Myocarditis Following a COVID-19 Messenger RNA Vaccination: A Japanese Case Series. *Intern Med*. doi:10.2169/internalmedicine.8731-21. <https://www.ncbi.nlm.nih.gov/pubmed/34840235>

- Nagasaka, T., Koitabashi, N., Ishibashi, Y., Aihara, K., Takama, N., Ohyama, Y., . . . Kaneko, Y. (2021). Acute Myocarditis Associated with COVID-19 Vaccination: A Case Report. *J Cardiol Cases*.
doi:10.1016/j.jccase.2021.11.006. <https://www.ncbi.nlm.nih.gov/pubmed/34876937>
- Ntouros, P. A., Vlachogiannis, N. I., Pappa, M., Nezos, A., Mavragani, C. P., Tektonidou, M. G., . . . Sfrikakis, P. P. (2021). Effective DNA damage response after acute but not chronic immune challenge: SARS-CoV-2 vaccine versus Systemic Lupus Erythematosus. *Clin Immunol*, 229, 108765.
doi:10.1016/j.clim.2021.108765. <https://www.ncbi.nlm.nih.gov/pubmed/34089859>
- Nygaard, U., Holm, M., Bohnstedt, C., Chai, Q., Schmidt, L. S., Hartling, U. B., . . . Stensballe, L. G. (2022). Population-based Incidence of Myopericarditis After COVID-19 Vaccination in Danish Adolescents. *Pediatr Infect Dis J*, 41(1), e25-e28.
doi:10.1097/INF.0000000000003389. <https://www.ncbi.nlm.nih.gov/pubmed/34889875>
- Oberhardt, V., Luxenburger, H., Kemming, J., Schulien, I., Ciminski, K., Giese, S., . . . Hofmann, M. (2021). Rapid and stable mobilization of CD8(+) T cells by SARS-CoV-2 mRNA vaccine. *Nature*, 597(7875), 268-273. doi:10.1038/s41586-021-03841-4. <https://www.ncbi.nlm.nih.gov/pubmed/34320609>
- Park, H., Yun, K. W., Kim, K. R., Song, S. H., Ahn, B., Kim, D. R., . . . Kim, Y. J. (2021). Epidemiology and Clinical Features of Myocarditis/Pericarditis before the Introduction of mRNA COVID-19 Vaccine in Korean Children: a Multicenter Study. *J Korean Med Sci*, 36(32), e232.
doi:10.3346/jkms.2021.36.e232. <https://www.ncbi.nlm.nih.gov/pubmed/34402230>
- Park, J., Brekke, D. R., & Bratincsak, A. (2021). Self-limited myocarditis presenting with chest pain and ST segment elevation in adolescents after vaccination with the BNT162b2 mRNA vaccine. *Cardiol Young*, 1-4.
doi:10.1017/S1047951121002547. <https://www.ncbi.nlm.nih.gov/pubmed/34180390>
- Patel, Y. R., Louis, D. W., Atalay, M., Agarwal, S., & Shah, N. R. (2021). Cardiovascular magnetic resonance findings in young adult patients with acute myocarditis following mRNA COVID-19 vaccination: a case series. *J Cardiovasc Magn Reson*, 23(1), 101.
doi:10.1186/s12968-021-00795-4. <https://www.ncbi.nlm.nih.gov/pubmed/34496880>
- Patone, M., Mei, X. W., Handunnetthi, L., Dixon, S., Zaccardi, F., Shankar-Hari, M., . . . Hippisley-Cox, J. (2021). Risks of myocarditis, pericarditis, and cardiac arrhythmias

associated with COVID-19 vaccination or SARS-CoV-2 infection. *Nat Med*.
doi:10.1038/s41591-021-01630-0. <https://www.ncbi.nlm.nih.gov/pubmed/34907393>

Patrignani, A., Schicchi, N., Calcagnoli, F., Falchetti, E., Ciampani, N., Argalia, G., & Mariani, A. (2021). Acute myocarditis following Comirnaty vaccination in a healthy man with previous SARS-CoV-2 infection. *Radiol Case Rep*, 16(11), 3321-3325.
doi:10.1016/j.radcr.2021.07.082. <https://www.ncbi.nlm.nih.gov/pubmed/34367386>

Perez, Y., Levy, E. R., Joshi, A. Y., Virk, A., Rodriguez-Porcel, M., Johnson, M., . . . Swift, M. D. (2021). Myocarditis Following COVID-19 mRNA Vaccine: A Case Series and Incidence Rate Determination. *Clin Infect Dis*.
doi:10.1093/cid/ciab926. <https://www.ncbi.nlm.nih.gov/pubmed/34734240>

Perrotta, A., Biondi-Zoccai, G., Saade, W., Miraldi, F., Morelli, A., Marullo, A. G., . . . Peruzzi, M. (2021). A snapshot global survey on side effects of COVID-19 vaccines among healthcare professionals and armed forces with a focus on headache. *Panminerva Med*, 63(3), 324-331. doi:10.23736/S0031-0808.21.04435-9.
<https://www.ncbi.nlm.nih.gov/pubmed/34738774>

Pinana, J. L., Lopez-Corral, L., Martino, R., Montoro, J., Vazquez, L., Perez, A., . . . Cell Therapy, G. (2022). SARS-CoV-2-reactive antibody detection after SARS-CoV-2 vaccination in hematopoietic stem cell transplant recipients: Prospective survey from the Spanish Hematopoietic Stem Cell Transplantation and Cell Therapy Group. *Am J Hematol*, 97(1), 30-42. doi:10.1002/ajh.26385. <https://www.ncbi.nlm.nih.gov/pubmed/34695229>

Revon-Riviere, G., Ninove, L., Min, V., Rome, A., Coze, C., Verschuur, A., . . . Andre, N. (2021). The BNT162b2 mRNA COVID-19 vaccine in adolescents and young adults with cancer: A monocentric experience. *Eur J Cancer*, 154, 30-34.
doi:10.1016/j.ejca.2021.06.002. <https://www.ncbi.nlm.nih.gov/pubmed/34233234>

Sanchez Tijmes, F., Thavendiranathan, P., Udell, J. A., Seidman, M. A., & Hanneman, K. (2021). Cardiac MRI Assessment of Nonischemic Myocardial Inflammation: State of the Art Review and Update on Myocarditis Associated with COVID-19 Vaccination. *Radiol Cardiothorac Imaging*, 3(6), e210252.
doi:10.1148/ryct.210252. <https://www.ncbi.nlm.nih.gov/pubmed/34934954>

Schauer, J., Buddhé, S., Colyer, J., Sagiv, E., Law, Y., Mallenahalli Chikkabyrappa, S., & Portman, M. A. (2021). Myopericarditis After the Pfizer Messenger Ribonucleic Acid

Coronavirus Disease Vaccine in Adolescents. *J Pediatr*, 238, 317-320.

doi:10.1016/j.jpeds.2021.06.083. <https://www.ncbi.nlm.nih.gov/pubmed/34228985>

Schneider, J., Sottmann, L., Greinacher, A., Hagen, M., Kasper, H. U., Kuhnen, C., . . . Schmeling, A. (2021). Postmortem investigation of fatalities following vaccination with COVID-19 vaccines. *Int J Legal Med*, 135(6), 2335-2345. doi:10.1007/s00414-021-02706-9. <https://www.ncbi.nlm.nih.gov/pubmed/34591186>

Schramm, R., Costard-Jackle, A., Rivinius, R., Fischer, B., Muller, B., Boeken, U., . . . Gummert, J. (2021). Poor humoral and T-cell response to two-dose SARS-CoV-2 messenger RNA vaccine BNT162b2 in cardiothoracic transplant recipients. *Clin Res Cardiol*, 110(8), 1142-1149. doi:10.1007/s00392-021-01880-5. <https://www.ncbi.nlm.nih.gov/pubmed/34241676>

Sessa, F., Salerno, M., Esposito, M., Di Nunno, N., Zamboni, P., & Pomara, C. (2021). Autopsy Findings and Causality Relationship between Death and COVID-19 Vaccination: A Systematic Review. *J Clin Med*, 10(24). doi:10.3390/jcm10245876. <https://www.ncbi.nlm.nih.gov/pubmed/34945172>

Sharif, N., Alzahrani, K. J., Ahmed, S. N., & Dey, S. K. (2021). Efficacy, Immunogenicity and Safety of COVID-19 Vaccines: A Systematic Review and Meta-Analysis. *Front Immunol*, 12, 714170. doi:10.3389/fimmu.2021.714170. <https://www.ncbi.nlm.nih.gov/pubmed/34707602>

Shay, D. K., Gee, J., Su, J. R., Myers, T. R., Marquez, P., Liu, R., . . . Shimabukuro, T. T. (2021). Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine – United States, March-April 2021. *MMWR Morb Mortal Wkly Rep*, 70(18), 680-684. doi:10.15585/mmwr.mm7018e2. <https://www.ncbi.nlm.nih.gov/pubmed/33956784>

Shazley, O., & Alshazley, M. (2021). A COVID-Positive 52-Year-Old Man Presented With Venous Thromboembolism and Disseminated Intravascular Coagulation Following Johnson & Johnson Vaccination: A Case-Study. *Cureus*, 13(7), e16383. doi:10.7759/cureus.16383. <https://www.ncbi.nlm.nih.gov/pubmed/34408937>

Shiyovich, A., Witberg, G., Aviv, Y., Eisen, A., Orvin, K., Wiessman, M., . . . Hamdan, A. (2021). Myocarditis following COVID-19 vaccination: magnetic resonance imaging study. *Eur Heart J Cardiovasc Imaging*. doi:10.1093/ehjci/jeab230. <https://www.ncbi.nlm.nih.gov/pubmed/34739045>

- Simone, A., Herald, J., Chen, A., Gulati, N., Shen, A. Y., Lewin, B., & Lee, M. S. (2021). Acute Myocarditis Following COVID-19 mRNA Vaccination in Adults Aged 18 Years or Older. *JAMA Intern Med*, 181(12), 1668-1670.
doi:10.1001/jamainternmed.2021.5511. <https://www.ncbi.nlm.nih.gov/pubmed/34605853>
- Singer, M. E., Taub, I. B., & Kaelber, D. C. (2021). Risk of Myocarditis from COVID-19 Infection in People Under Age 20: A Population-Based Analysis. *medRxiv*.
doi:10.1101/2021.07.23.21260998. <https://www.ncbi.nlm.nih.gov/pubmed/34341797>
- Smith, C., Odd, D., Harwood, R., Ward, J., Linney, M., Clark, M., . . . Fraser, L. K. (2021). Deaths in children and young people in England after SARS-CoV-2 infection during the first pandemic year. *Nat Med*. doi:10.1038/s41591-021-01578-1. <https://www.ncbi.nlm.nih.gov/pubmed/34764489>
- Snapiri, O., Rosenberg Danziger, C., Shirman, N., Weissbach, A., Lowenthal, A., Ayalon, I., . . . Bilavsky, E. (2021). Transient Cardiac Injury in Adolescents Receiving the BNT162b2 mRNA COVID-19 Vaccine. *Pediatr Infect Dis J*, 40(10), e360-e363.
doi:10.1097/INF.0000000000003235. <https://www.ncbi.nlm.nih.gov/pubmed/34077949>
- Spinner, J. A., Julien, C. L., Olayinka, L., Dreyer, W. J., Bocchini, C. E., Munoz, F. M., & Devaraj, S. (2021). SARS-CoV-2 anti-spike antibodies after vaccination in pediatric heart transplantation: A first report. *J Heart Lung Transplant*.
doi:10.1016/j.healun.2021.11.001. <https://www.ncbi.nlm.nih.gov/pubmed/34911654>
- Starekova, J., Bluemke, D. A., Bradham, W. S., Grist, T. M., Schiebler, M. L., & Reeder, S. B. (2021). Myocarditis Associated with mRNA COVID-19 Vaccination. *Radiology*, 301(2), E409-E411.
doi:10.1148/radiol.2021211430. <https://www.ncbi.nlm.nih.gov/pubmed/34282971>
- Sulemankhil, I., Abdelrahman, M., & Negi, S. I. (2021). Temporal association between the COVID-19 Ad26.COV2.S vaccine and acute myocarditis: A case report and literature review. *Cardiovasc Revasc Med*.
doi:10.1016/j.carrev.2021.08.012. <https://www.ncbi.nlm.nih.gov/pubmed/34420869>
- Tailor, P. D., Feighery, A. M., El-Sabawi, B., & Prasad, A. (2021). Case report: acute myocarditis following the second dose of mRNA-1273 SARS-CoV-2 vaccine. *Eur Heart J Case Rep*, 5(8), ytab319.
doi:10.1093/ehjcr/ytab319. <https://www.ncbi.nlm.nih.gov/pubmed/34514306>

- Takeda, M., Ishio, N., Shoji, T., Mori, N., Matsumoto, M., & Shikama, N. (2021). Eosinophilic Myocarditis Following Coronavirus Disease 2019 (COVID-19) Vaccination. *Circ J.* doi:10.1253/circj.CJ-21-0935. <https://www.ncbi.nlm.nih.gov/pubmed/34955479>
- Team, C. C.-R., Food, & Drug, A. (2021). Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine – United States, December 14-23, 2020. *MMWR Morb Mortal Wkly Rep*, 70(2), 46-51. doi:10.15585/mmwr.mm7002e1. <https://www.ncbi.nlm.nih.gov/pubmed/33444297>
- Thompson, M. G., Burgess, J. L., Naleway, A. L., Tyner, H., Yoon, S. K., Meece, J., . . . Gaglani, M. (2021). Prevention and Attenuation of Covid-19 with the BNT162b2 and mRNA-1273 Vaccines. *N Engl J Med*, 385(4), 320-329. doi:10.1056/NEJMoa2107058. <https://www.ncbi.nlm.nih.gov/pubmed/34192428>
- Tinoco, M., Leite, S., Faria, B., Cardoso, S., Von Hafe, P., Dias, G., . . . Lourenco, A. (2021). Perimyocarditis Following COVID-19 Vaccination. *Clin Med Insights Cardiol*, 15, 11795468211056634. doi:10.1177/11795468211056634. <https://www.ncbi.nlm.nih.gov/pubmed/34866957>
- Truong, D. T., Dionne, A., Muniz, J. C., McHugh, K. E., Portman, M. A., Lambert, L. M., . . . Newburger, J. W. (2021). Clinically Suspected Myocarditis Temporally Related to COVID-19 Vaccination in Adolescents and Young Adults. *Circulation*. doi:10.1161/CIRCULATIONAHA.121.056583. <https://www.ncbi.nlm.nih.gov/pubmed/34865500>
- Tutor, A., Unis, G., Ruiz, B., Bolaji, O. A., & Bob-Manuel, T. (2021). Spectrum of Suspected Cardiomyopathy Due to COVID-19: A Case Series. *Curr Probl Cardiol*, 46(10), 100926. doi:10.1016/j.cpcardiol.2021.100926. <https://www.ncbi.nlm.nih.gov/pubmed/34311983>
- Umei, T. C., Kishino, Y., Shiraishi, Y., Inohara, T., Yuasa, S., & Fukuda, K. (2021). Recurrence of myopericarditis following mRNA COVID-19 vaccination in a male adolescent. *CJC Open*. doi:10.1016/j.cjco.2021.12.002. <https://www.ncbi.nlm.nih.gov/pubmed/34904134>
- Vidula, M. K., Ambrose, M., Glassberg, H., Chokshi, N., Chen, T., Ferrari, V. A., & Han, Y. (2021). Myocarditis and Other Cardiovascular Complications of the mRNA-Based COVID-19 Vaccines. *Cureus*, 13(6), e15576. doi:10.7759/cureus.15576. <https://www.ncbi.nlm.nih.gov/pubmed/34277198>

Visclosky, T., Theyyunni, N., Klekowski, N., & Bradin, S. (2021). Myocarditis Following mRNA COVID-19 Vaccine. *Pediatr Emerg Care*, 37(11), 583-584.

doi:10.1097/PEC.0000000000002557. <https://www.ncbi.nlm.nih.gov/pubmed/34731877>

Warren, C. M., Snow, T. T., Lee, A. S., Shah, M. M., Heider, A., Blomkalns, A., . . . Nadeau, K. C. (2021). Assessment of Allergic and Anaphylactic Reactions to mRNA COVID-19 Vaccines With Confirmatory Testing in a US Regional Health System. *JAMA Netw Open*, 4(9), e2125524.

doi:10.1001/jamanetworkopen.2021.25524. <https://www.ncbi.nlm.nih.gov/pubmed/34533570>

Watkins, K., Griffin, G., Septaric, K., & Simon, E. L. (2021). Myocarditis after BNT162b2 vaccination in a healthy male. *Am J Emerg Med*, 50, 815 e811-815 e812.

doi:10.1016/j.ajem.2021.06.051. <https://www.ncbi.nlm.nih.gov/pubmed/34229940>

Weitzman, E. R., Sherman, A. C., & Levy, O. (2021). SARS-CoV-2 mRNA Vaccine Attitudes as Expressed in U.S. FDA Public Commentary: Need for a Public-Private Partnership in a Learning Immunization System. *Front Public Health*, 9, 695807.

doi:10.3389/fpubh.2021.695807. <https://www.ncbi.nlm.nih.gov/pubmed/34336774>

Welsh, K. J., Baumblatt, J., Chege, W., Goud, R., & Nair, N. (2021). Thrombocytopenia including immune thrombocytopenia after receipt of mRNA COVID-19 vaccines reported to the Vaccine Adverse Event Reporting System (VAERS). *Vaccine*, 39(25), 3329-3332.

doi:10.1016/j.vaccine.2021.04.054. <https://www.ncbi.nlm.nih.gov/pubmed/34006408>

Witberg, G., Barda, N., Hoss, S., Richter, I., Wiessman, M., Aviv, Y., . . . Kornowski, R. (2021). Myocarditis after Covid-19 Vaccination in a Large Health Care Organization. *N Engl J Med*, 385(23), 2132-2139.

doi:10.1056/NEJMoa2110737. <https://www.ncbi.nlm.nih.gov/pubmed/34614329>

Zimmermann, P., & Curtis, N. (2020). Why is COVID-19 less severe in children? A review of the proposed mechanisms underlying the age-related difference in severity of SARS-CoV-2 infections. *Arch Dis Child*. doi:10.1136/archdischild-2020-

320338. <https://www.ncbi.nlm.nih.gov/pubmed/33262177>

<https://www.saveusnow.org.uk/covid-vaccine-scientific-proof-lethal/>

Beautiful work by saveusnow; superb! Helps us with this scholarship.

VAERS Analysis

Weekly analysis of the
VAERS data

EXHIBIT S

VAERS WEEKLY SUMMARY

VAERS Summary for COVID-19 Vaccines through 11/19/2021

○ DEC 1, 2021

Download as PDF

All charts and tables below reflect the data release on 11/29/2021 from the VAERS website, which includes U.S. and foreign data, and is updated through: 11/19/2021

High-Level Summary	COVID19 vaccines (Dec'2020 – present)	All other vaccines 1990-present	US Data Only COVID19 vaccines (Dec'2020 – present)	US Data Only All other vaccines 1990-present
Number of Adverse Reactions	913,268	857,017	664,745	747,775
Number of Life-Threatening Events	21,582	14,113	10,223	9,848
Number of Hospitalizations	97,561	81,699	41,501	38,608
Number of Deaths	19,249*	9,286	8,898	5,199
# of Permanent Disabilities after vaccination	30,967	20,387	10,232	12,702
Number of Office Visits	143,275	47,797	128,111	45,912
# of Emergency Room/Department Visits	101,315	211,713	83,101	202,367



***CDC

DISCLAIMER
ON VAERS***

[How Do I Know If The
Data On This Website Is
Accurate?](#)



RECENT POSTS

[VAERS Summary for
COVID-19 Vaccines
through 12/17/2021](#)

[VAERS Summary for
COVID-19 Vaccines
through 12/10/2021](#)

[Minor Improvement to
Weekly Update
Reports \(and the CDC
Sux at Data Quality
Control\)](#)

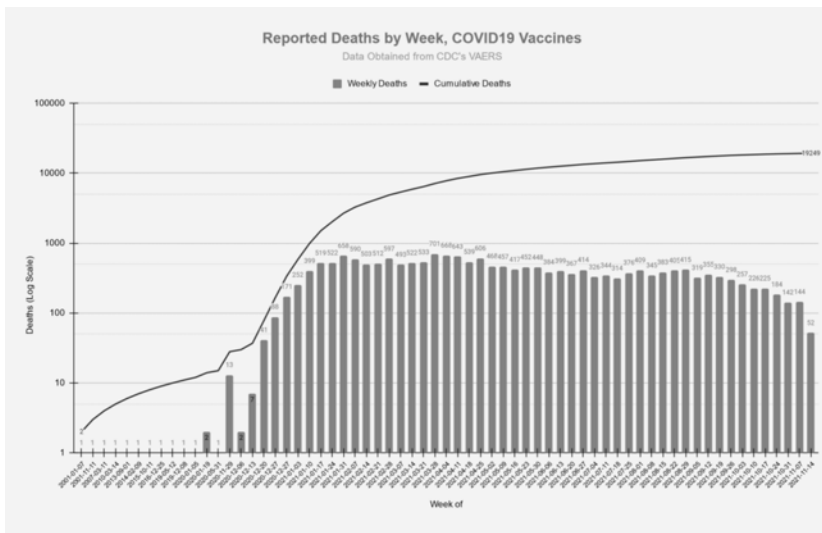
[Using CMS
Whistleblower Data to
Approximate the
Under-Reporting
Factor for VAERS —
Part II](#)



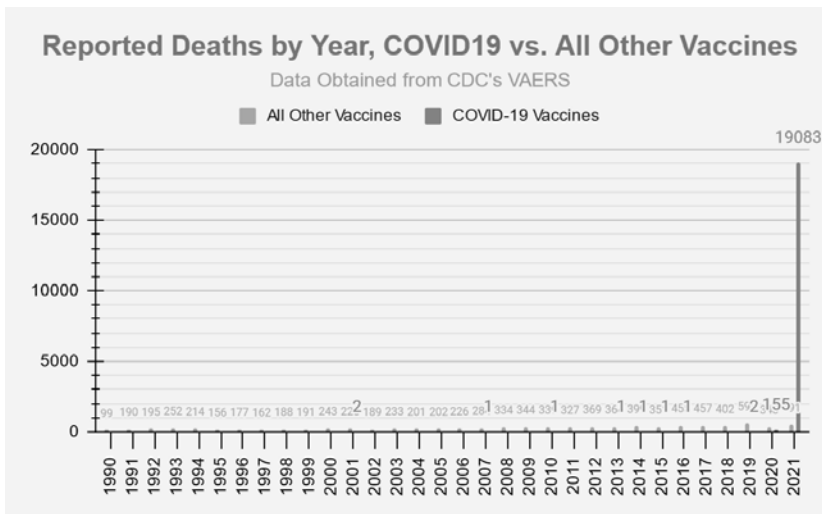
High-Level Summary	COVID19 vaccines (Dec'2020 – present)	All other vaccines 1990-present	US Data Only COVID19 vaccines (Dec'2020 – present)	US Data Only All other vaccines 1990-present
# of Birth Defects after vaccination	671	172	391	98

*Note that the total number of deaths associated with the COVID-19 vaccines is more than double the number of deaths associated with all other vaccines combined since the year 1990.

Deaths



[Note that the single counts before 2020-11-29 are due to incorrect date data in the VAERS system]



[Note that COVID19 counts for years before 2020 are due to incorrect date data in the VAERS system (including 1 not pictured due to date in 1921)]

[Using CMS Whistleblower Data to Approximate the Under-Reporting Factor for VAERS](#)

[VAERS Summary for COVID-19 Vaccines through 12/03/2021](#)

[***CDC SCRUBS Death Record of a 2-Year Old from Latest VAERS Release \(12/3/21\)***](#)

[VAERS Summary for COVID-19 Vaccines through 11/26/2021](#)

[VAERS Summary for COVID-19 Vaccines through 11/19/2021](#)

[WelcomeTheEagle88's Extra Data](#)

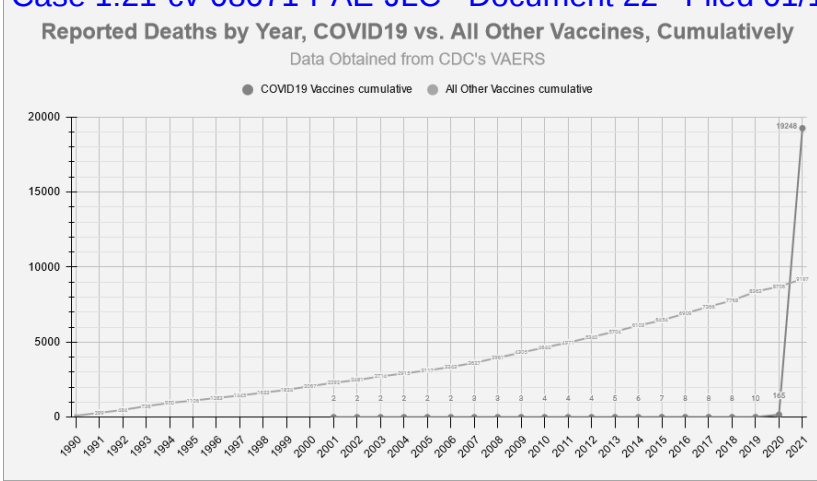
RECENT COMMENTS

[MUST READ: "By Complying with the COVID-19 Guidelines I Would Be Participating in Terrorism" - Remote Jobs on VAERS Summary for COVID-19 Vaccines through 12/03/2021](#)

[Yonason on VAERS Summary for COVID-19 Vaccines through 12/17/2021](#)

["By Complying with the COVID-19 Guidelines I Would Be Participating in Terrorism" – VA Nurse Sends Out Letter and Compared the Guidelines as an 'Act of Terrorism' on VAERS Summary for COVID-19 Vaccines through 12/03/2021](#)

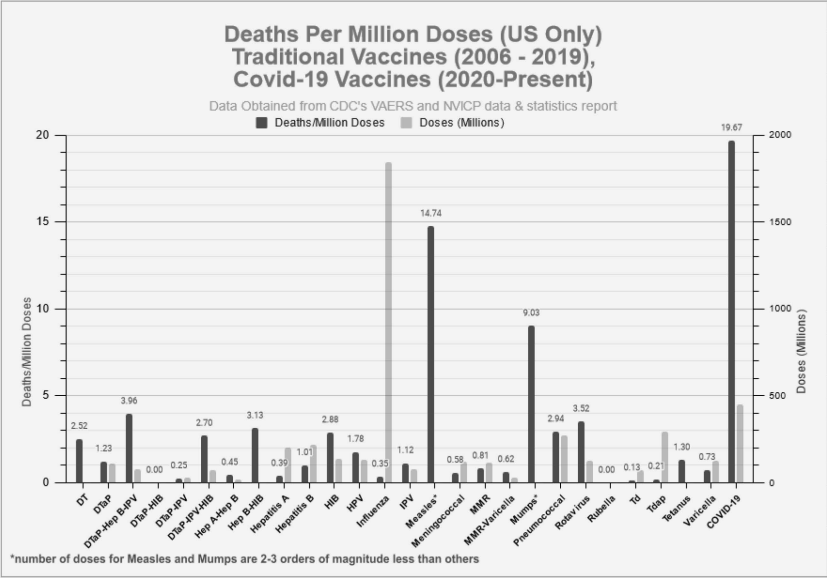
[Yonason on VAERS Summary for COVID-19 Vaccines through 12/17/2021](#)



Yonason on [VAERS](#)
Summary for COVID-19 Vaccines through
12/17/2021

[1 COVID19 record not pictured due to incorrect date in 1921]

Chart using comparable 11 month periods, since Covid-19 vaccines have only been available for approximately 11 months:



Adverse Events

Note that 991 records for COVID19 were scattered throughout years earlier than 2020 due to incorrect date data in the VAERS system]

Chart using comparable 11 month periods, since Covid-19 vaccines have only been available for approximately 11 months:



Symptoms

The slide below was taken from an FDA document from October 22, 2020 and provides a list of possible adverse event outcomes related to the Covid-19 vaccines.

- Source: 'Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Presentation'.



FDA Safety Surveillance of COVID-19 Vaccines :

DRAFT Working list of possible adverse event outcomes

*****Subject to change*****

▪ Guillain-Barré syndrome	▪ Deaths
▪ Acute disseminated encephalomyelitis	▪ Pregnancy and birth outcomes
▪ Transverse myelitis	▪ Other acute demyelinating diseases
▪ Encephalitis/myelitis/encephalomyelitis/meningoencephalitis/meningitis/encephalopathy	▪ Non-anaphylactic allergic reactions
▪ Convulsions/seizures	▪ Thrombocytopenia
▪ Stroke	▪ Disseminated intravascular coagulation
▪ Narcolepsy and cataplexy	▪ Venous thromboembolism
▪ Anaphylaxis	▪ Arthritis and arthralgia/joint pain
▪ Acute myocardial infarction	▪ Kawasaki disease
▪ Myocarditis/pericarditis	▪ Multisystem Inflammatory Syndrome in Children
▪ Autoimmune disease	▪ Vaccine enhanced disease

The following table lists the number of adverse events found in the VAERS data which match the outcomes listed above:

FDA Listed Symptom	Total (Non-Lethal) Adverse Events	Total Deaths
Guillain-Barre	1769	32
Acute Disseminated Encephalomyelitis	123	3
Transverse Myelitis	310	2
Encephalitis	1445	146
Convulsions/Seizures	11526	334
Stroke	10946	987
Narcolepsy, Cataplexy	230	4
Anaphylaxis	39606	155
Acute Myocardial Infarction (Heart Attack)	3158	965
Myocarditis/Pericarditis	11449	144
Autoimmune Disease	1008	19
Other Acute Demyelinating Diseases	231	3
Pregnancy and birth outcomes (Miscarriages)	2880	84
Other Allergic Reactions	1729	3
Thrombocytopenia	3899	291
Disseminated Intravascular Coagulation	169	51
Venous Thromboembolism	16842	927
Arthritis and Arthralgia/Joint Pain	59827	174
Kawasaki Disease	44	1

FDA Listed Symptom	Total (Non-Lethal) Adverse Events	Total Deaths
Systemic Inflammatory Response Syndrome	527	39

Vaccination Related Risks of COVID19 Vs. Flu

These set of figures compare the COVID19 vaccine to the traditional Flu vaccines.

'Risk of Death' percentages depend on the '# of Vaccinations' data, which is only approximate, and was pulled from the [CDC's report](#) on Flu vaccination coverage for the 2019-2020 season, and from [Our World in Data](#) for the COVID19 vaccinations.

**Covid19 vaccinations through 5/31/2021 vs. Flu vaccinations 7/1/2019 – 5/31/2020
(last complete flu season)**

Vaccine Type	# of Vaccinations ^[3]	# of Deaths	Risk of Death	Percentage	Deaths/Mill. Vaccinations ¹
Flu	167,447,642 ^[1]	32	1 in 5,232,739	0.000019%	.19
COVID19	167,733,972 ^[2]	5,571	1 in 30,108	0.003321%	33.21

Risk of dying from COVID vaccine is 174 times greater than Flu Vaccine

Vaccine Type	# of Vaccinations ^[3]	# of Adverse Reactions	Risk of Adverse Reaction	Percentage	AEs/Mill. Vaccinations ¹
Flu	167,447,642	9,707	1 in 17,250	0.005797%	57.97
COVID19	167,733,972	528,165	1 in 318	0.3149%	3,149

Risk of adverse reaction from COVID vaccine is 54 times greater than Flu Vaccine

^[1] number of flu vaccinations based on estimated flu vaccine coverage data from [CDC](#) and estimated population data from [US Census](#). Yearly flu vaccination data covers a period of time from 7/1 to 5/31 of the following year.

^[2] number of covid19 vaccinations based on estimates from [Our World in Data](#) ^[2] number of covid19 vaccinations based on estimates from [Our World in Data](#)

^[3] Persons vaccinated with at least one dose.

Vaccine Data by Manufacturer

Manufacturer	# of Deaths	% Deaths	Average Deaths/Day	# US Deaths	US Doses Administered	Average US Deaths per Dose
Janssen (JNJ)	1575	8.18%	5.92	1018	16,597,641	6
Moderna	4746	24.64%	14.13	3749	175,430,932	2
Pfizer/Biontech	12867	66.8%	37.51	4100	266,730,650	1
Unknown	73	0.38%		39	475,568	

Manufacturer	# of AEs	% AEs	Average AEs/Day	# US AEs	US Doses Administered	Average US AEs per Dose
Janssen (JNJ)	68818	7.52%	258.71	59814	16,597,641	3603
Moderna	340302	37.21%	1012.8	307879	175,430,932	1754
Pfizer/Biontech	503448	55.05%	1467.78	296649	266,730,650	1112
Unknown	2002	0.22%		1506	475,568	

Vaccine Data by Gender

Vaccine Data by Location



Recall History



Sources

1. Vaccine data (Covid-19 and other vaccines) taken from CDC's VAERS website, located here: <https://vaers.hhs.gov/data/datasets.html>. VAERS data sets in the form of csv files are pulled down weekly and put into a database for reporting/analysis. Data files are available all the way back to 1990.
2. Number of doses distributed for other vaccines found in NVICP Data and Statistics report here: <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/data-statistics-report.pdf>
3. Numbers for Covid-19 vaccines administered by manufacturer found here: https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total
4. Numbers for total Covid-19 vaccine doses administered found here: <https://data.cdc.gov/Vaccinations/COVID-19-Vaccination-Trends-in-the-United-States-N/rh2h-3yt2>
5. Numbers for Flu vaccine doses administered for 2019-2020 season found here: <https://www.cdc.gov/flu/fluview/coverage-1920estimates.htm>
6. Numbers for FDA regulated drugs taken from FDA's FAERS website, located here: <https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard>



« [VAERS Summary for COVID-19 Vaccines through 11/26/2021](#) [VAERS Summary for COVID-19 Vaccines through 11/12/2021](#) »



RELATED POST

Summary for
COVID-19
Vaccines
through
12/17/2021

DEC 25, 2021

WAYNETHEDBA

Summary for
COVID-19
Vaccines
through
12/10/2021

DEC 18, 2021

WAYNETHEDBA

Reports (and
the CDC Sux
at Data
Quality
Control)

DEC 18, 2021

WAYNETHEDBA

15 thoughts on “VAERS Summary for COVID-19 Vaccines through 11/19/2021”

Chicago Mayor Lightfoot Humiliated As She Revokes Vaccine

Mandate says:

December 2, 2021 at 10:07 am

[...] VAERS, the Vaccine Adverse Reaction database, shows roughly one million reactions to the COVID-19 vaccines, and even children are dying as a result. In Vietnam, at least three children have died after [...]

REPLY

Full Stop to this Deadly Psychopathic Clown Show - Caprice Thorsen

says:

December 3, 2021 at 2:10 pm

[...] VAERS summary for Covid-19 adverse reactions and deaths (updated weekly). [...]

REPLY

“We are in Deep Trouble!” Following the Science behind the COVID

Catastrophe - 10z viral says:

December 4, 2021 at 10:03 pm

[...] year, skilled medical doctors and researchers hold aloft studies and statistics, including the recent VAERS statistics tabulating injuries and deaths to the COVID and other vaccines. They are dismissed with [...]

REPLY



"We are in Deep Trouble!" Following the Science behind the COVID

Catastrophe – Biz Patriot says:

December 4, 2021 at 10:04 pm

[...] medical doctors and researchers hold aloft studies and statistics, including the recent VAERS statistics tabulating injuries and deaths to the COVID and other vaccines. They are dismissed with [...]

REPLY

If you believe 'my body, my choice,' you should be against abortion

AND forced vaccines | Christian Liberty Network says:

December 6, 2021 at 7:32 pm

[...] And, as evidenced by U.S. Food and Drug Administration (FDA) warnings and reports submitted to the U.S. government's Vaccine Adverse Event Reporting System (VAERS), not a [...]

REPLY

Tyranny With A Needle | by Kelleigh Nelson December 7, 2021 A strict observance of the written laws is doubtless one of the high duties of a good citizen, but it is not the highest. The laws of necessity, of self-preservation, of saving our country when i says:

December 6, 2021 at 11:49 pm

[...] we saw with the swine flu in 1976. We have lost thousands in America alone. Scroll through the VAERS summary for Covid jabs, remembering this is only one percent of reported deaths or adverse [...]

REPLY



Ro says:

December 28, 2021 at 4:25 am

They report only 1% of death?? How is that possible????

REPLY

Tyranny with a Needle - Dr. Rich Swier says:

December 7, 2021 at 7:39 am

[...] we saw with the swine flu in 1976. We have lost thousands in America alone. Scroll through the VAERS summary for Covid jabs, remembering this is only one percent of reported deaths or adverse [...]

REPLY



Freedoms Being Steadily Eroded – Dare to Seek the Truth says:

December 7, 2021 at 11:25 am

[...] therapeutic. And, as evidenced by U.S. Food and Drug Administration (FDA) warnings and reports submitted to the U.S. government's Vaccine Adverse Event Reporting System (VAERS), not a [...]

REPLY

TYRANNY WITH A NEEDLE – Chugley's Chatter says:

December 7, 2021 at 2:42 pm

[...] with the swine flu in 1976. We have lost thousands in America alone. Scroll through the VAERS summary for Covid jabs, remembering this is only one percent of reported deaths or adverse effects. [...]

REPLY



marcia Ostrander says:

December 13, 2021 at 3:49 pm

my son (43) was diagnosed with pancreatitis. He does not drink or smoke. Would be consider obese.
Has been double vax'd, not sure about booster. As of this am, told his pancreous showed 50% of his pancreous is necrotic.
Last week through imaging there was a small amount of necrosis. Was told it might have been from a a gallstone that got hung up somewhere. Though inspite of all the imaging they can not show any in the imaging.
He is in excruciating pain, has gone from morhine to dilauted and back I think to morphine.
Is now back on dilauted. He has an NG tube (small bowel seems to backing up into Stomach.)
He had a feeding tube put in, told they by-passed the stomach and placed it in the colon. He was showing signs of malnutrition. He had a kidney stone a couple years ago nothing like this before.
Am also wodering if clots or micro clots could have caused this ???

REPLY



WayneTheDBA says:

December 13, 2021 at 4:24 pm

Very sorry to hear about your son. IMHO, it is certainly possible, but given his medical history, perhaps not as clear-cut. Go here and search for pancreatitis (and its variations):
<https://vaersanalysis.info/2021/11/24/all-the-symptoms/>



You will see that while pancreatitis events are certainly

elevated over what we usually see in VAERS reported for other vaccines, so are multitudes of other symptoms; this particular symptom isn't in the top 1000 symptoms on the list. Best bet is to seek medical advice from a doc who understands and is sympathetic to covid vax injuries.

REPLY

Ne faites pas vacciner vos enfants contre le virus de Wuhan. Les chiffres sont catastrophiques. – NTIC says:

December 20, 2021 at 2:29 am

[...] Résumé VAERS pour les vaccins COVID-19 jusqu'au 19/11/2021 <https://vaersanalysis.info/2021/12/01/vaers-summary-for-covid-19-vaccines-through-11-19-2021/> [...]

REPLY

Korona aşıları hakkındaki iddialar ve gerçekler | EuroNur :

SaidNursi.de says:

December 21, 2021 at 12:41 am

[...] 19.11.2021 TARİHİNE KADAR AŞI YAN ETKİ RAPORU [...]

REPLY



Joseph King says:

December 26, 2021 at 7:39 pm

These Scumbags pushing this experimental death shot know exactly whats going on its a plan for Global depopulation, anyone who disagrees with the facts is helping to perpetrate the lie and are guilty also, bring back the death penalty!

REPLY

Leave a Reply

Your email address will not be published. Required fields are marked *



Comment

Name *

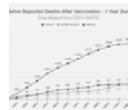
Email *

Website

☐ Save my name, email, and website in this browser for the next time I comment.

Post Comment

PREVIOUS POSTS



VAERS WEEKLY
SUMMARY

**VAERS
Summary for
COVID-19
Vaccines
through
12/17/2021**

VAERS WEEKLY
SUMMARY

**VAERS
Summary for
COVID-19
Vaccines
through
12/10/2021**

VAERS WEEKLY
SUMMARY

**Minor
Improvement
to Weekly**

POSTS

**Using CMS
Whistleblower
Data to**



[Update Reports
\(and the CDC
Sux at Data
Quality Control\)](#)

[Approximate
the Under-
Reporting
Factor for
VAERS — Part II](#)

POSTS

[Using CMS
Whistleblower
Data to
Approximate
the Under-
Reporting
Factor for
VAERS](#)

VAERS WEEKLY
SUMMARY

[VAERS
Summary for
COVID-19
Vaccines
through
12/03/2021](#)



POSTS

[***CDC SCRUBS
Death Record
of a 2-Year Old
from Latest
VAERS Release
\(12/3/21\)***](#)

VAERS WEEKLY
SUMMARY

[VAERS
Summary for
COVID-19
Vaccines
through
11/26/2021](#)

VAERS WEEKLY
SUMMARY

[VAERS
Summary for
COVID-19
Vaccines
through
11/19/2021](#)

UNCATEGORIZED

[WelcomeTheEa
gle88's Extra
Data](#)

VAERS Analysis

Weekly analysis of the VAERS data





~~EXHIBIT X~~ EXHIBIT T

MENU

Log in to Patient Account

Request an Appointment

Find a Doctor

Find a Job

Give Now

English

Patient Care & Health Information Diseases & Conditions

Smallpox

Request an
Appointment

Symptoms & causes Diagnosis & treatment

Overview

[Print](#)

Advertisement

Smallpox is a contagious, disfiguring and often deadly disease that has affected humans for thousands of years. Naturally occurring smallpox was wiped out worldwide by 1980 — the result of an unprecedented global immunization campaign.

Samples of smallpox virus have been kept for research purposes. And advances in synthetic biology have made it possible to create smallpox from published amino acid sequences. This has led to concerns that smallpox could someday be used as a biological warfare agent.

No cure or treatment for smallpox exists. A vaccine can prevent smallpox, but the risk of the vaccine's side effects is too high to justify routine vaccination for people at low risk of exposure to the smallpox virus.

Products & Services

[Book: Mayo Clinic Family Health Book, 5th Edition](#)

Show more products from Mayo Clinic

Symptoms

The first symptoms of smallpox usually appear 10 to 14 days after you're infected. During the incubation period of seven to 17 days, you look and feel healthy and can't infect others.



Smallpox

Following the incubation period, a sudden onset of flu-like signs and symptoms occurs. These include:

- Fever
- Overall discomfort
- Headache
- Severe fatigue
- Severe back pain
- Vomiting, possibly

A few days later, flat, red spots appear first on your face, hands and forearms, and later on your trunk. Within a day or two, many of these lesions turn into small blisters filled with clear fluid, which then turns into pus. Scabs begin to form eight to nine days later and eventually fall off, leaving deep, pitted scars.

Lesions also develop in the mucous membranes of your nose and mouth and quickly turn into sores that break open.

Request an Appointment at Mayo Clinic

Causes

Smallpox is caused by infection with the variola virus. The virus can be transmitted:

- **Directly from person to person.** Direct transmission of the virus requires fairly prolonged face-to-face contact. The virus can be transmitted through the air by droplets that escape when an infected person coughs, sneezes or talks.
- **Indirectly from an infected person.** In rare instances, airborne virus can spread farther, possibly through the ventilation system in a building, infecting people in other rooms or on other floors.

Mayo Clinic does not endorse companies or products. Advertising revenue supports our not-for-profit mission.

Advertising & Sponsorship

Policy | Opportunities | Ad Choices

Mayo Clinic Press

Check out these best-sellers and special offers on books and newsletters from Mayo Clinic Press.

NEW – Cook Well, Eat Less

FREE Mayo Clinic Diet Assessment

Mayo Clinic Health Letter - FREE book

Live Younger Longer

Back and Neck Health



- **Via contaminated items.** Smallpox can also spread through contact with contaminated clothing and bedding, although the risk of infection from these sources is less common.
- **As a terrorist weapon, potentially.** A deliberate release of smallpox is a remote threat. However, because any release of the virus could spread the disease quickly, government officials have taken numerous precautions to protect against this possibility, such as stockpiling smallpox vaccine.

Complications

Most people who get smallpox survive. However, a few rare varieties of smallpox are almost always fatal. These more-severe forms most commonly affect pregnant women and people with impaired immune systems.

People who recover from smallpox usually have severe scars, especially on the face, arms and legs. In some cases, smallpox may cause blindness.

Prevention

In the event of an outbreak, people who had smallpox would be kept in isolation in an effort to control the spread of the virus. Anyone who had contact with someone who developed an infection would need a smallpox vaccine, which can prevent or lessen the severity of the disease if given within four days of exposure to the smallpox virus.

Two vaccines are available. One vaccine (ACAM2000) uses a live virus that's related to smallpox, and it can occasionally cause serious complications, such as infections affecting the heart or brain. That's why it's not recommended that everyone be vaccinated at this time. The potential risks of the vaccine outweigh the benefits, in the absence of an actual smallpox outbreak.

A second vaccine, a modified vaccinia Ankara vaccine (Jynneos), has been found to be safe, and it can be used in people who aren't able to take ACAM2000, who have weakened immune systems or who have skin disorders.

If you were vaccinated as a child

Immunity or partial immunity after a smallpox vaccine may last up to 10 years, and 20 years with revaccination. If an outbreak ever occurred, people who were vaccinated as children would still likely receive a new vaccination after direct exposure to someone with the virus.

Request an Appointment at Mayo Clinic

Diagnosis & treatment

Share on: Facebook Twitter Print Sept. 22, 2020

Show references

Related

Smallpox

Products & Services

Book: Mayo Clinic Family Health Book, 5th Edition

Show more products and services from Mayo Clinic

Smallpox

Symptoms & causes

Diagnosis & treatment



- Request Appointment | Contact Us
- About Mayo Clinic | Employees | Find a Job
- Site Map | About This Site

Mayo Clinic is a not-for-profit organization. Make a donation.

Privacy Policy

Notice of Privacy Practices

Notice of Nondiscrimination